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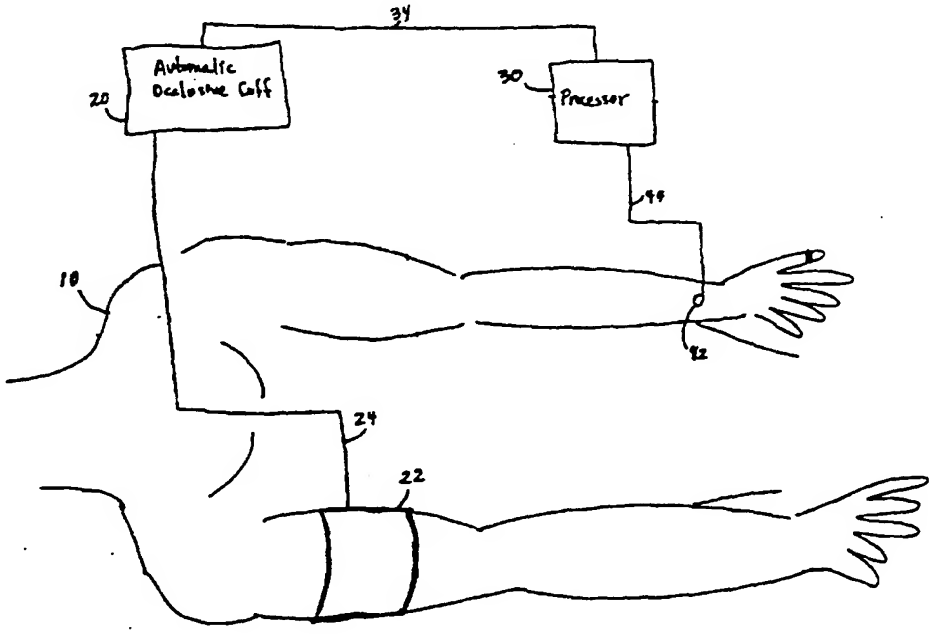
(54) Title: AUTOMATICALLY ACTIVATED BLOOD PRESSURE MEASUREMENT DEVICE



(57) Abstract

A monitor for activating a sphygmomanometer (20, 22) attached to a patient includes a sensor (42, 52, 62A, 62B) to generate a sensor signal indicative of a physi logical parameter. The sensor (42, 52, 62A, 62B) can be, for example, a non-invasive sensor (42, 52, 62A, 62B) that generates a signal responsive to blood pressure. The monitor also has a processor (30) coupled to the sensor (42, 52, 62A, 62B) and to the sphygmomanometer (20, 22). The processor (30) is configured to process the sensor signal and to send a signal to activate the sphygmomanometer (20, 22) when the sensor signal meets predetermined criteria.

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AUTOMATICALLY ACTIVATED BLOOD PRESSURE MEASUREMENT DEVICE

Related Applications

This patent application is a continuation-in-part of Caro et al., U.S. Patent Application Ser. No. 08/228,213 filed April 15, 1994.

Field of the Invention

The present invention relates to an apparatus and method for automatically activating a blood pressure measurement device depending on a variety of sensed physiological parameters including a patient's blood pressure and other clinically important parameters.

Background of the Invention

Blood pressure is the force within the arterial system of an individual that ensures the flow of blood and delivery of oxygen and nutrients to the tissue. Prolonged reduction or loss of pressure severely limits the amount of tissue perfusion and could therefore result in damage to or even death of the tissue. Although some tissues can tolerate hypoperfusion for long periods of time, the brain, heart and kidneys are very sensitive to a reduction in blood flow. Thus, during and after surgery, blood pressure is a frequently monitored vital sign. Blood pressure is affected, during and after surgery, by the type of surgery and physiological factors such as the body's reaction to the surgery. Moreover, blood pressure

is manipulated and controlled, during and aft r surgery, using various medications. Often, these physiological factors and the given medications can result in a situation of rapidly changing blood pressure requiring immediate blood pressure measurement, and corrective action.

Because of changes in the patient's blood pressure, constant monitoring is important. The traditional method of measuring blood pressure is with a stethoscope, occlusive cuff and pressure manometer. However, this technique is slow, subjective in nature, requires the intervention of a skilled clinician and does not provide timely readings frequently required in critical situations.

For these reasons, two methods of measuring blood pressure have been developed: noninvasive, intermittent methods that use an automated sphygmomanometer or cuff device such as an oscillometric cuff; and invasive, continuous (beat-to-beat) measurements that use a catheter and pressure transducer.

The cuff device typically requires 15 to 45 seconds to obtain a measurement, and should allow sufficient time for venous recovery. Too frequent cuff inflations over extended periods may result in ecchymosis and/or nerve damage in the area underlying the cuff. For this reason, periodic cuff measurements should not be taken more often than approximately once every 5 minutes. This is an inordinately long amount of time to wait for an updated pressure reading when fast acting medications are administered. The invasive method has inherent disadvantages including risk of embolization, infection, bleeding and vessel wall damage.

To address the need for continuous, noninvasive blood pressure measurement, several systems were developed. One system relies on blood pressure values in a patient's finger as indicative of the patient's central blood pressure. Another syst m uses two cuffs, one on each arm, to determine calibration readings and continuous readings

respectively. Another system transforms a time sampled blood pressure waveform into the frequency domain and determines blood pressure based on deviations of the fundamental frequency. Kaspari et al., U.S. Patent Application Ser. No. 08/177,448, filed January 5, 1994 provides examples of these systems.

Objects and Summary of the Invention

The present invention describes an apparatus and method for automatically activating a sphygmomanometer depending on a variety of parameters including a patient's blood pressure and other clinically important parameters.

An object of the present invention is to continuously monitor a sensor signal that is responsive to changes in the patient's blood pressure. A related object is to activate a cuff device when the sensor signal meets predetermined criteria.

Another object of the present invention is to induce a perturbation into a patient's blood or blood vessel and to continuously monitor a sensor signal that is responsive to changes in the patient's blood pressure. A related object is to activate a cuff device when the sensor signal meets predetermined criteria.

A monitor for activating a sphygmomanometer attached to a patient includes a sensor attached to the patient to generate a sensor signal representative of a physiological parameter. This sensor can be, for example, a noninvasive sensor that generates a signal responsive to blood pressure. The monitor also has a processor coupled to the sensor and to the sphygmomanometer. The processor is configured to process the sensor signal and to send a signal to activate the sphygmomanometer when the sensor signal meets predetermined criteria.

In operation, the monitor initially activates the sphygmomanometer to obtain a blood pressure measurement. Thereafter, the sphygmomanometer is activated manually by a doctor or nurse, automatically at predetermined time intervals, or when the processor determines that the

sensor signal indicates that the patient's blo d pressur is sufficiently different from that previously measured.

Brief Description of the Figures

Figure 1 depicts a first embodiment of the present invention attached to a patient;

Figure 2 depicts a flowchart showing the procedures involved in monitoring the patient for the first embodiment;

Figure 3 depicts a second embodiment of the present invention attached to a patient;

Figure 4 depicts a third embodiment of the present invention attached to a patient;

Figure 5 depicts a flowchart showing the procedures involved in monitoring the patient for the third embodiment;

Figure 6 depicts a fourth embodiment of the present invention attached to a patient;

Figure 7 depicts a fifth embodiment of the present invention attached to a patient;

Figure 8 depicts a sixth embodiment of the present invention attached to a patient;

Figure 9 depicts a seventh embodiment of the present invention attached to a patient;

Figure 10 depicts a flowchart showing the procedures involved in monitoring the patient for the seventh embodiment;

Figure 11 depicts an eighth embodiment of the present invention attached to a patient; and

Figure 12 depicts a processor for monitoring the patient according to the present invention.

Detailed Description of the Preferred Embodiments

The embodiments described operate by sensing specific physiological parameters to automatically activate a sphygmomanometer. However, it should be understood that the present invention is directed toward a device that operates by sensing any of a plurality of physiological

parameters to detect a change in the patient's blood pressure and to activate a blood pressure measuring device. In this context, the sphygmomanometer of the preferred embodiments can be substituted with any device capable of measuring blood pressure.

Those skilled in the art will appreciate that various changes and modifications can be made to the embodiments while remaining within the scope of the present invention. Moreover, currently pending patent applications incorporated herein by reference are Kaspari et al., U.S. Patent Application Ser. No. 08/177,448 filed January 5, 1994, and Caro et al., U.S. Patent Application Ser. No. 08/228,213 filed April 15, 1994.

A first embodiment is explained with reference to Figures 1 and 2. A patient 10 is shown with an sphygmomanometer 20, 22, attached to the upper arm. The sphygmomanometer includes the control unit 20 and the cuff 22. The cuff 22 is attached to the control unit 20 via a trunk 24 that controls the inflation of the cuff 22 and receives signals from the cuff regarding the systolic and diastolic blood pressure. This type of automatic cuff is known in the art, however, an explanation of the operation is given for clarity.

In operation, the cuff 22 is attached to one of the patient's limbs, such as an arm or leg. It is even possible that the cuff be attached to the same limb as that to which any sensor is attached. The cuff is first pressurized to abate the blood flow in the limb. Then, as the pressure is slowly reduced, a transducer senses when the blood flow begins and this pressure is recorded as the systolic pressure. As the pressure is further reduced, the transducer similarly detects when full blood flow is restored and this pressure is recorded as the diastolic pressure. The signals representing pressure are delivered, via trunk 24 to control unit 20.

A processor 30 is coupled to the sphygmomanometer control unit 20 via cable 34. The processor 30 receives information regarding the patient's blood pressure from

the control unit 20, and can activate th control unit 20 via the cable 34. The processor 30 is also coupled to a noninvasive sensor 42 via cable 44. The sensor 42 is a piezoelectric sensor that generates a signal related to the blood pressure at the sensor site. In Figure 1, th sensor 42 is shown attached over the radial artery, but can be placed over any artery that is close to the skin surface. The sensor 42 generates a signal that is communicated to the processor 30 via cable 44.

A user sets a periodic measurement interval time for the sphygmomanometer, which can range from 2-60 minutes or longer. Then, the user initializes the processor 30 which begins the procedural flowchart 100 with step 102 by initializing the processor input signals. The processor 30 sends an initialization signal to the cuff control unit 20 to obtain a blood pressure measurement. The control unit 20, in turn, activates the cuff 22 and determines the blood pressure of the patient 10. Simultaneously, in step 104, the processor 30 receives the sensor signal from the sensor 42 and stores a record of the signal during measurement. Alternatively the processor stores a record of the sensor signal just before measurement or just after measurement.

During the time between measurements, in step 106, the processor 30 then receives a continuous signal from the sensor 42. The processor 30, in step 108, continuously compares the continuous sensor signal to the stored sensor signal taken during measurement. This comparison can include a comparison of periodicity, peak value, low value, waveshape, or any other factors. If, for example, waveshape is used, the processor 30 can compare the relative start time, peak time and ending time against the stored signal. If the chosen parameters conform with the testing criteria, or are within a defined bounds, then the processor continues to receive the continuous sensor signal and to compare it against the stored signal. However, if one or more of these parameters changes, the processor may determine that the

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patient's blood pressure has changed since the last measurement and may move to st p 110 where the processor 30 sends a signal to the control unit 20 to perform a blood pressure measurement. This is the equivalent of an initial measurement as performed in step 102 and the iterative procedure begins again.

Figure 3 depicts a second embodiment using a photoplethysmograph. One type of photoplethysmograph, for example, is an oximeter control unit 50 coupled to an oximeter sensor 52 via cable 54. The oximeter sensor 52 performs a similar function to the noninvasive sensor 42 of the first embodiment by measuring the blood flow in a patient's extremity. The processor takes the oximeter sensor signal and performs the same procedure 100 to activate the sphygmomanometer control unit 20 as described in the first embodiment. Photoplethysmograph sensors are known in the art, and a good discussion of their functions is described in C.M. Alexander, Principles of Pulse Oximetry: Theoretical and Practical Considerations, Anesth Analg vol. 68 p. 368-376 (International Anesthesia Research Society 1989). In general, they shine light through an appendage, such as a finger or earlobe, and measure the attenuation of the light. The attenuation of the light has a direct relationship to the amount of oxygen in the blood, and the amount of oxygen in the blood has a direct relationship to the patient's pulse.

A third embodiment is described with reference to Figures 4 and 5. A sphygmomanometer is attached to the patient similar to the first embodiment. In this embodiment, however, the processor 30 is coupled to two sensors. The processor 30 is coupled to a noninvasive arterial sensor 42 and an electrocardiogram (ECG) unit 60, which is attached to sensor 62A and 62B via cables 64A and 64B respectively. The purpose of this configuration is to measure the time difference of arrival of the pulse at different points of the body.

A known relationship exists between pressure and velocity of a pulse. This is defined by equation 1:

$$V \propto A + BP$$

where V is velocity, A and B are constants and P is pressure. The velocity versus pressure curve is monotonic but not necessarily linear. However, the curve can be represented as piecewise linear over a range sufficient to be used in the present invention. The times of arrival at the first sensor (T_1) and at the second sensor (T_2) are subtracted to determine a time difference of arrival (TDOA). This equation is used to determine a change in blood pressure over time. Many factors are involved in the relationship between the TDOA and pressure, such as heart strength, arterial flexibility, length between the sensors and others, and they vary from patient to patient. However, since for any single patient the variables remain substantially constant for all practical purposes during the monitoring time, these factors do not need to be quantified for each patient.

Turning to the flowchart 200, the measurement step 202 is performed by activating the cuff control unit 20 and then in step 204a and 204b by receiving the ECG signal from the ECG unit 60 and receiving the noninvasive sensor signal from the noninvasive sensor 42. Then the time difference is calculated by the processor 30 in step 206, and that value is stored.

The processor continuously receives the sensor signals from the ECG unit 60 and the noninvasive sensor 42 in step 208a and 208b, and continuously determines the TDOA in step 210. A comparison of the continuous TDOA and the stored TDOA is performed in step 212. If, according the equation 1, a change in TDOA is within predetermined bounds, then the continuous monitoring continues. An example of criteria used to determine if the TDOA is within bounds is a TDOA change of 10%, a change of 20%, or a change of 30% or more. The specific criteria can be altered and may differ depending on many factors including

the patient's health, the type of surgery, the type of anesthetic and other factors.

If the processor determines that a change occurs outside a predetermined bound, then, in step 214, the processor sends a signal to the control unit 20 to initiate a new measurement. Execution of the measurement returns the processing to step 202.

Figure 6 depicts a fourth embodiment similar to the third embodiment. The ECG unit 60 is replaced with a photoplethysmograph, such as an oximeter unit 50. The procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 7 depicts a fifth embodiment similar to the third embodiment. The noninvasive sensor 40 is replaced with a photoplethysmograph, such as an oximeter unit 50. The procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 8 depicts a sixth embodiment similar to the third embodiment, but using an additional third sensor. The addition of the third sensor can be used, for example, to refine the time difference between pulse arrival at the first and second, second and third, and first and third sensors. Again, the procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 9 depicts a seventh embodiment that uses an induced perturbation to determine whether a change in blood pressure occurs. This embodiment uses the time delay between a known exciter waveform and a sensor to monitor a change in the patient's blood pressure. An exciter 72 is attached to one of the patient's limbs, such as to the forearm above the radial artery. The exciter 72 is a device for inducing a mechanical perturbation of the patient's body tissue, and can be a device such as an inflatable bag fixed in place near an accessible artery by a holddown device such as a buckle, adhesive strap or

other device. Moreover, the exciter is controlled by the processor 30 via air tube 74. Alternatively, the excit r can be an electro-mechanical device such as a piezoelectric exciter or a solenoid exciter or other similar device, where the air tube is replaced with a wire.

The perturbation excites the tissue and blood vessel below the exciter and causes a perturbation waveform to radiate within the patient's body, at least a portion of which travels in the arterial blood. Experiments conducted to determine a range of satisfactory perturbation frequencies found that the range of 20-600Hz works well. It is anticipated that frequencies of lesser than 20Hz and greater than 600Hz will also work well, and it is intended that this specification cover all frequencies insofar as the present invention is novel.

Figure 9 further shows a noninvasive sensor 42 placed at a distance from the exciter on the patient's wrist. The noninvasive sensor is connected to the processor 30 via cable 44. As is shown, the sensor is positioned ov r the radial artery and it is responsive to pressure variations therein. As the pressure increases, the piezoelectric material deforms and generates a signal corresponding to the deformation.

Since a known relationship exists between blood pressure and exciter waveform velocity, a deviation in the time of transit indicates a change in blood pressure. Also, at a given frequency many other relationships are known: a relationship exists between velocity and wavelength, the greater the velocity the longer the wavelength; and a relationship exists between wavelength and phase, a change in wavelength will result in a proportional change in phase. As a result, the exciter signal is continuously measured by the sensor and a comparison is continuously made against the sensor signal stored at measurement to determine if the patient's blood pressure changes.

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Referring to Figure 10, a flow chart 300 shows the procedure used to determine whether the patient's blood pressure changes. First, the exciter signal is generated by the processor and transmitted to the exciter. A measurement step 302 activates the sphygmomanometer control unit 20 and determines the patient's blood pressure, as described above. Then the processor stores the sensor signal at measurement in step 304. In step 306, the processor continuously receives the sensor signal.

In step 308, the processor then continuously compares the continuous sensor signal to the sensor signal stored at measurement to determine if the blood pressure changes. This determination can be based on many factors including the time since the last measurement, whether the linearity of the velocity/pressure curve is outside of a reliable range, determination by medical personnel that a new measurement is desired or other factors. As an example of these factors, the embodiments provide user settable measurement time intervals of 2-60 minutes or more. For a periodic exciter waveform a known relationship exits between the phase of the continuous sensor signal and the blood pressure. This is represented by equation 2:

$$\Phi \propto C + DP$$

where Φ is phase, C and D are constants and P is pressure. The phase change as related to blood pressure also depends on the wavelength and frequency of the exciter wave, referring to the first equation which relates pressure and velocity. Moreover, the phase versus pressure curve is not necessarily linear, but the curve can be represented as piecewise linear over a range sufficient to be used in the present invention. Therefore, in step 308, the processor determines whether the sensor signal is valid within a predetermined phase change and within a predetermined pi cewise linear region of the phase/pressure curve. If the continuous sensor signal is within bounds, the processing continues to step 306.

Step 310 is performed when step 308 determines that the prior measur ment is no longer reliable as describ d above, such as the periodic time is expired or the patient's blood pressure changes beyond a predetermined bound. After step 310 is performed, the processing returns to step 304.

Figure 11 depicts an eighth embodiment showing th noninvasive sensor replaced by an oximeter sensor 52. This embodiment is similar to the seventh embodiment and the flowchart 300 is applicable to show the procedure for employing this embodiment.

With regard to all the embodiments, Figure 12 depicts a processor 30 that can perform the functions of receiving the sensor signals and processing the sensor signals to determine when to activate the sphygmomanometer. The processor includes a noninvasive sensor interface 40 to receive the noninvasive sensor signal. An oximeter interface 50 is for receiving the oximeter sensor signal. An ECG interface 60 is for receiving the ECG sensor signal, which can include a plurality of inputs for a plurality of ECG sensors. An exciter interface 70 is for sending a signal to the exciter to cause a perturbation wave in the patient. A sphygmomanometer interface 80 is to receive readings from the cuff transducers and to activate the cuff when required. And, a spare interface 90 is included to receive or transmit signals to other sensors or processors.

All the device interfaces are coupled to a central processing unit (CPU) 82 and a memory 84. Moreover, a user interface 86 is included to receive input from a user and to display any required information to the user on a display 88. One skilled in the art will recognize that the processor 30 is a general purpose type computer specially configured with interfaces for required device interfaces -- depending on the embodiment -- and programmed to perform the procedures set forth in the present invention -- again, depending on the embodiment.

Alternately, processor 30 can be specially designed to perform the functions described in the invention.

VARIATIONS ON THE DISCLOSED EMBODIMENTS

Various noninvasive sensors have been developed for sensing a variety of physiological parameters. These sensor types include piezoelectric, piezoresistive, impedance plethysmograph, photoplethysmograph, various types of strain gauges, air cuffs, tonometry, conductivity, resistivity and other devices. Also, many invasive sensors can be used with the present invention, if so desired. The present invention can use any sensor that provides a waveform related to the physiological parameter of interest.

Having disclosed a preferred embodiment and the best mode, modifications and variations may be made to the disclosed embodiments without departing from the subject and spirit of the invention as defined by the following claims.

CLAIMS

What is claim d is:

1. A monitor for indicating a change in a patient's blood pressure, comprising:

a first sensor attached to the patient to generate a first signal representative of a physiological parameter of the patient; and

a processor coupled to said first sensor and configured to process said first signal and to generate a signal indicating a change in the patient's blood pressure when said first signal meets predetermined criteria.

2. The monitor of claim 1, wherein:

said predetermined criteria includes waveshape criteria.

3. The monitor of claim 1, wherein:

said first sensor is a noninvasive arterial sens r configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient.

4. The monitor of claim 1, wherein:

said first sensor is a photoplethysmograph sensor configured to generate said first signal responsive to a change in the volume of blood in an artery of the patient.

5. The monitor of claim 1, further comprising:

a sphygmomanometer attached to the patient and coupled to said processor; and

wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

6. The monitor of claim 1, further comprising:

a second sensor attached to the patient to generate a second signal representative of a second physiological parameter of the patient; and

wherein said processor is further coupled to said second sensor and further configured to process said

second signal and to generate a signal indicating a change in the patient's blood pressure when said first signal and said second signal meet predetermined criteria.

7. The monitor of claim 6, wherein:
said predetermined criteria includes time difference of arrival criteria.

8. The monitor of claim 6, wherein:
said first sensor is an ECG sensor configured to generate said first signal responsive to electrical impulses in the chest of the patient; and
said second sensor is a noninvasive arterial sensor configured to generate said second signal responsive to a change in arterial pressure in an artery of the patient.

9. The monitor of claim 6, wherein:
said first sensor is an ECG sensor configured to generate said first signal responsive to electrical impulses in the chest of the patient; and
said second sensor is a photoplethysmograph sensor configured to generate said second signal responsive to a change in the volume of blood in an artery of the patient.

10. The monitor of claim 6, wherein:
said first sensor is a noninvasive arterial sensor configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient; and
said second sensor is a photoplethysmograph sensor configured to generate said second signal responsive to a change in the volume of blood in an artery of the patient.

11. The monitor of claim 6, further comprising:
a sphygmomanom ter attached to the patient and coupled to said processor; and
wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

12. A monitor for indicating a change in a patient's blood pressure, comprising:

an exciter attached to the patient to generate a perturbation in said patient;

a sensor attached to the patient to generate a sensor signal representative of a physiological parameter of the patient; and

a processor coupled to said exciter and to said sensor and configured to process said sensor signal and to generate a signal indicating a change in the patient's blood pressure when said sensor signal meets predetermined criteria.

13. The monitor of claim 12, wherein:

said predetermined criteria includes phase change criteria.

14. The monitor of claim 12, wherein:

said sensor is a noninvasive arterial sensor configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient.

15. The monitor of claim 12, wherein:

said sensor is a photoplethysmograph sensor configured to generate said first signal responsive to a change in the volume of blood in an artery of the patient.

16. The monitor of claim 12, further comprising:

a sphygmomanometer attached to the patient and coupled to said processor; and

wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

17. A method of determining when a patient's blood pressure changes and generating a signal indicating a change in the patient's blood pressure, comprising the steps of:

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sensing a first physiological parameter of the patient;

generating a first signal representative of the first physiological parameter of the patient;

processing the first signal; and

when said first signal meets predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

18. The method of claim 17, wherein:

said step of processing said first signal is performed by comparing said first signal to predetermined criteria including waveshape criteria.

19. The method of claim 17, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

20. The method of claim 17, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

21. The method of claim 17, further comprising the step of:

when the signal indicating a change in the patient's blood pressure is generated, activating a sphygmomanometer.

22. The method of claim 17, further comprising the steps of:

sensing a second physiological parameter of the patient;

generating a second signal r presentative of the second physiological parameter of the patient;

processing the second signal; and

when said first signal and said second signal meet predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

23. The method of claim 22, wherein:

said step of processing said first signal and said step of processing said second signal are performed by comparing said first signal and said second signal to predetermined criteria including time difference of arrival criteria.

24. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing the ECG of the patient; and

said step of sensing a second physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

25. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing the ECG of the patient; and

said step of sensing a second physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

26. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient; and

said step of sensing a second physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

27. The method of claim 22, further comprising the step of:

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when the signal indicating a change in the patient's blood pressure is generated, activating a sphygmomanometer.

28. A method of determining when a patient's blood pressure changes and generating a signal indicating a change in the patient's blood pressure, comprising the steps of:

generating a perturbation in the patient;

sensing a first physiological parameter of the patient;

generating a first signal representative of the first physiological parameter of the patient;

processing the first signal; and

when said first signal meets predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

29. The method of claim 28, wherein:

said step of processing the first signal is performed by comparing said first signal to predetermined criteria including signal phase criteria.

30. The method of claim 28, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

31. The method of claim 28, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

32. The method of claim 28, further comprising the step of:

when the signal indicating a change in the pati nt's blood pressure is generated, activating a sphygmomanometer.

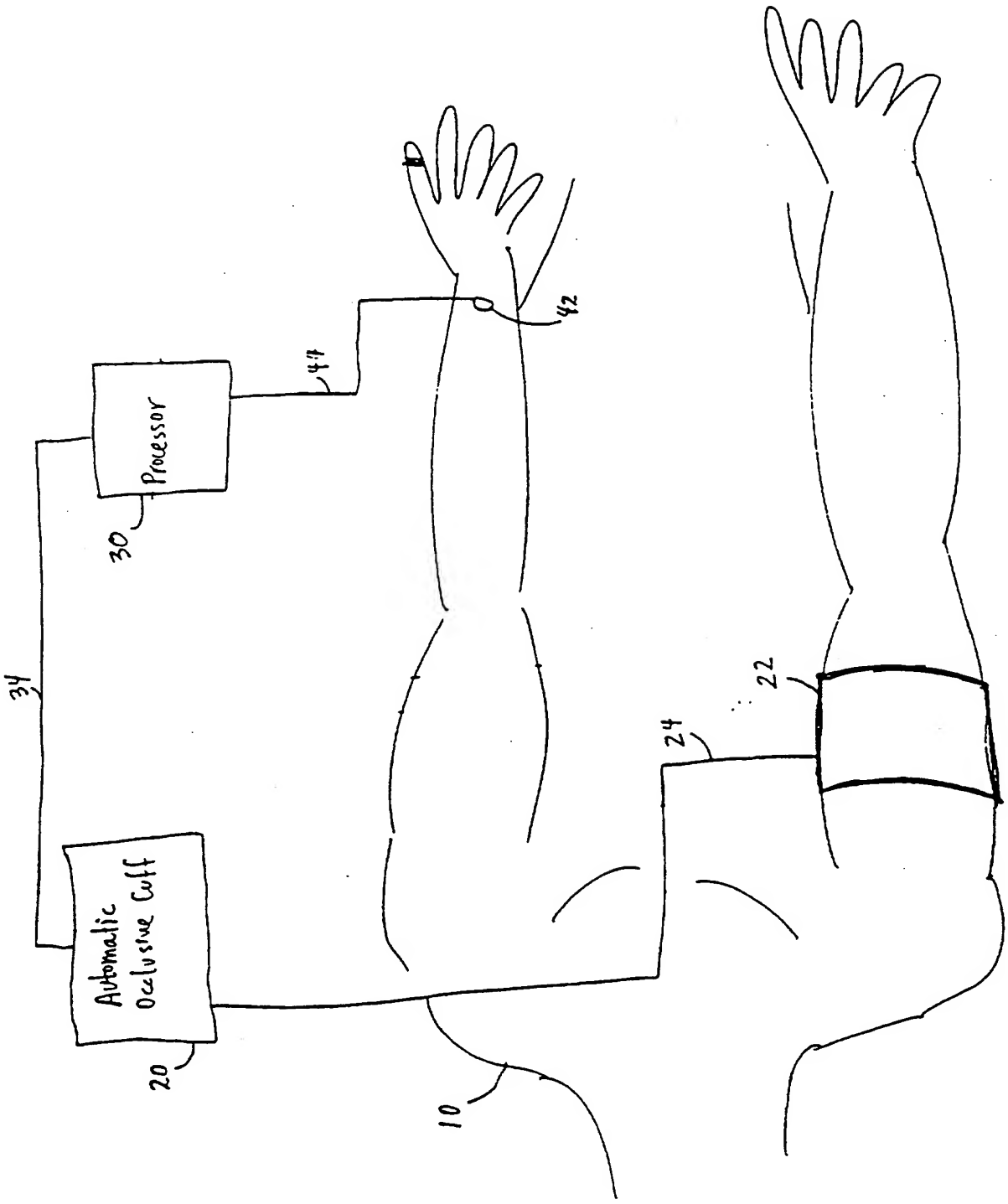

FIG 1

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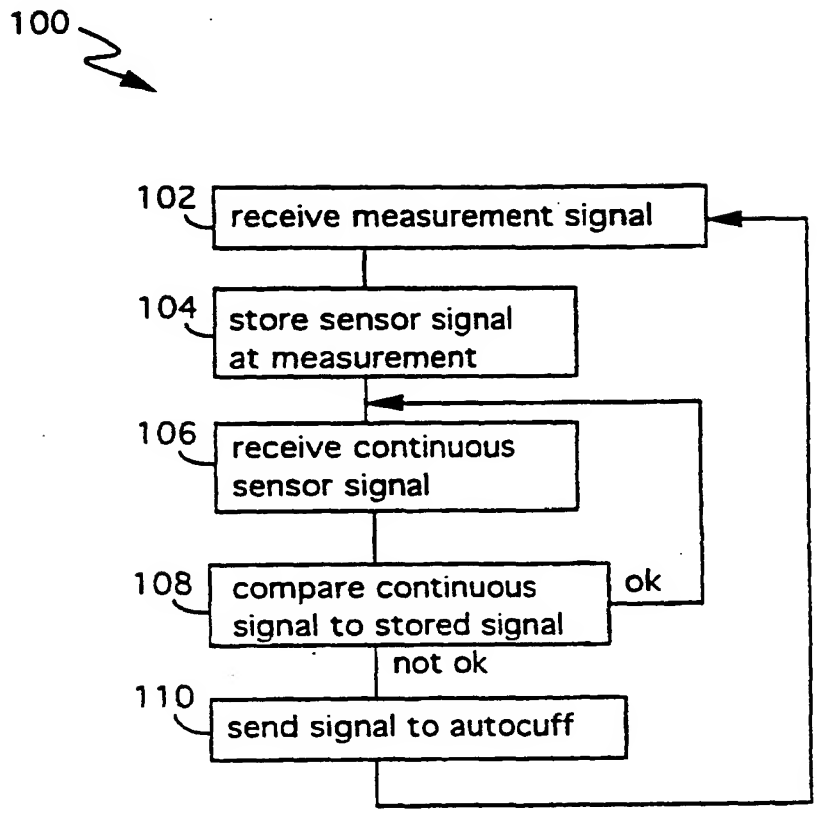
100
102
receive measurement signal
104
store sensor signal at measurement
106
receive continuous sensor signal
108
compare continuous signal to stored signal
ok
not ok
110
send signal to autocuff

Figure 2

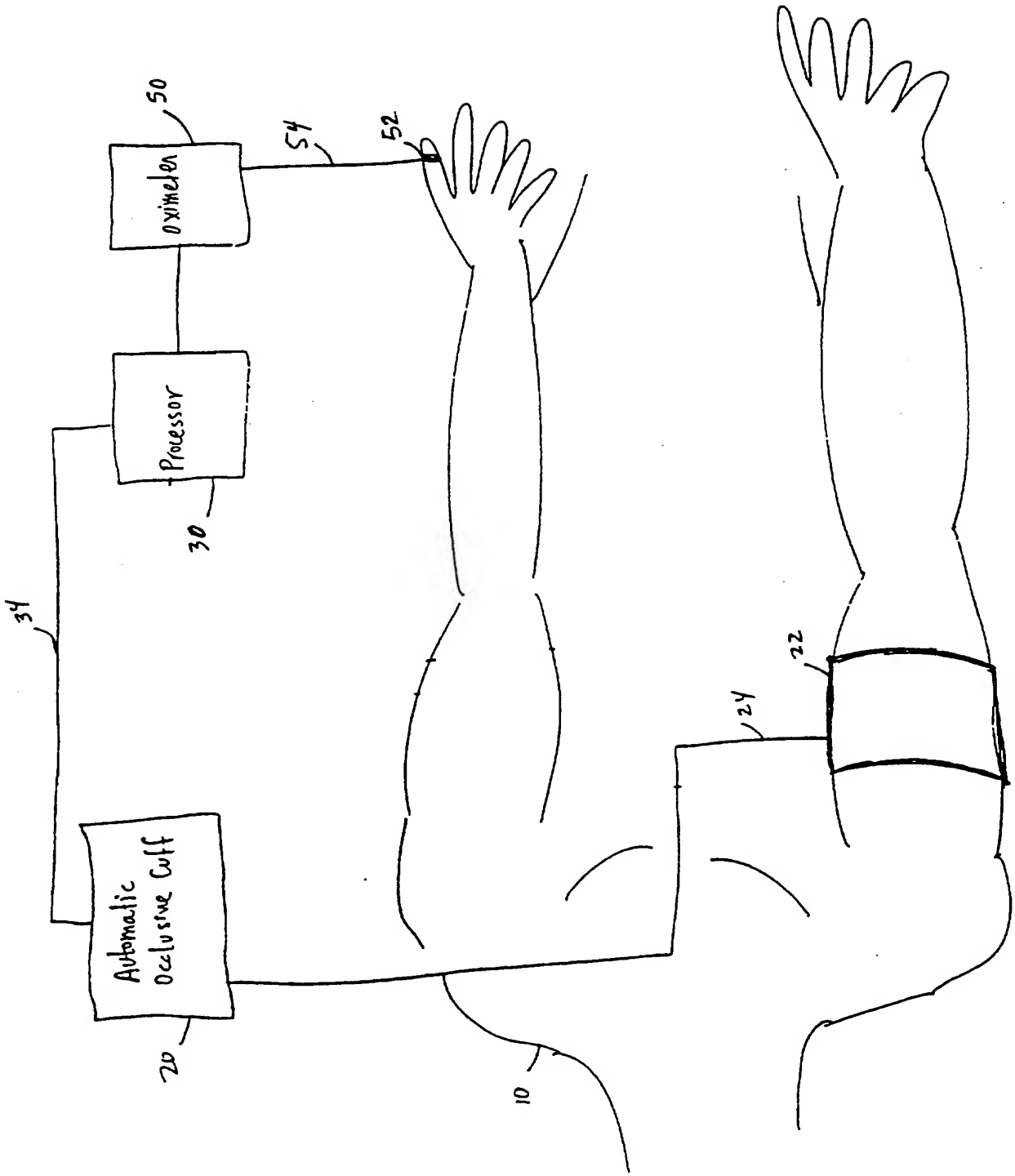
50
Oximeter
54
52
Processor
30
34
Automatic
Occlusive Cuff
20
10
22
24

FIG 3

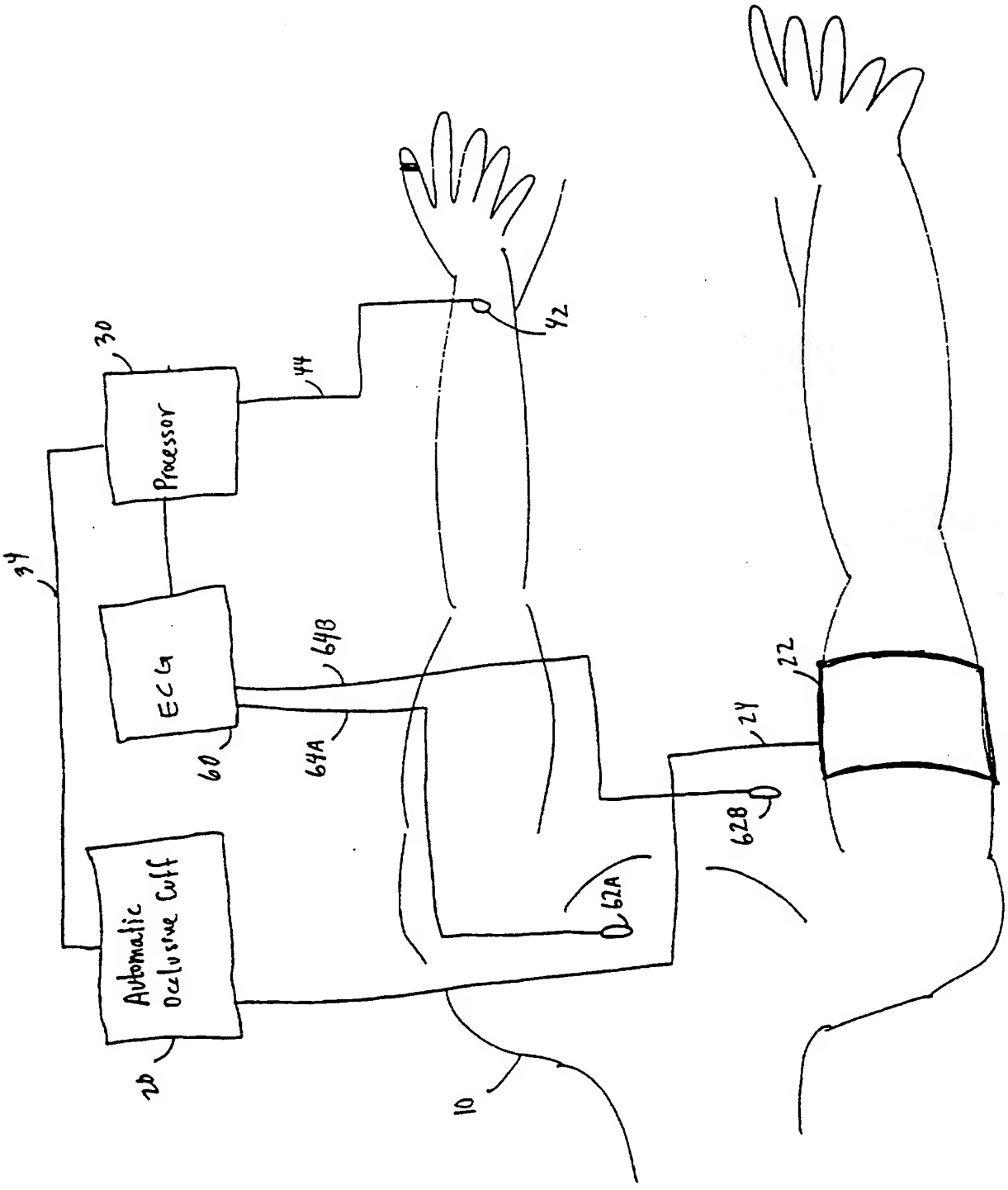
Processor
ECG
Automatic Occlusive Cuff
30
44
42
34
64B
64A
60
20
10
62A
62B
24
22

FIG 4

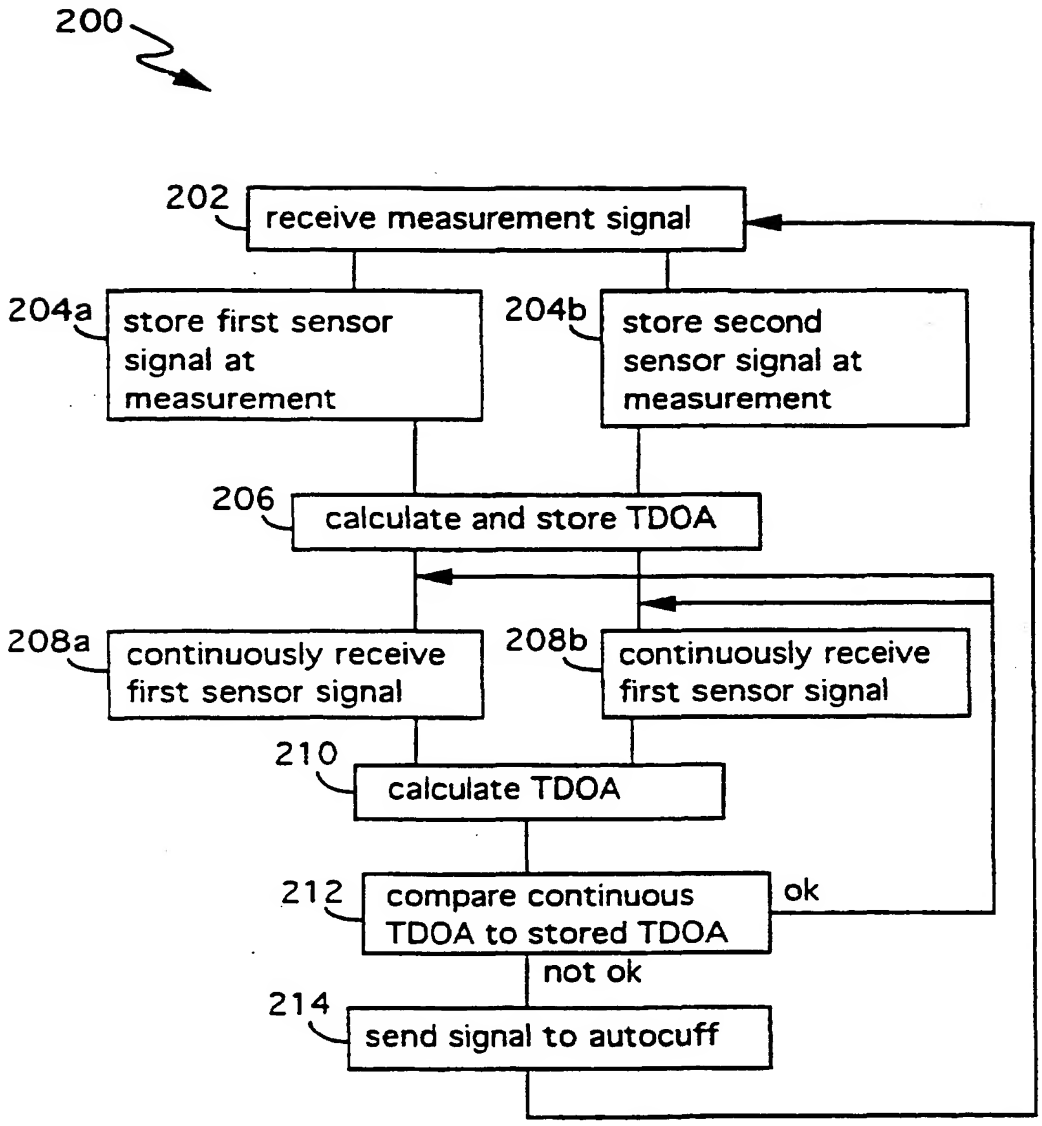
200
202
receive measurement signal
204a
store first sensor signal at measurement
204b
store second sensor signal at measurement
206
calculate and store TDOA
208a
continuously receive first sensor signal
208b
continuously receive first sensor signal
210
calculate TDOA
212
compare continuous TDOA to stored TDOA
ok
not ok
214
send signal to autocuff

Figure 5

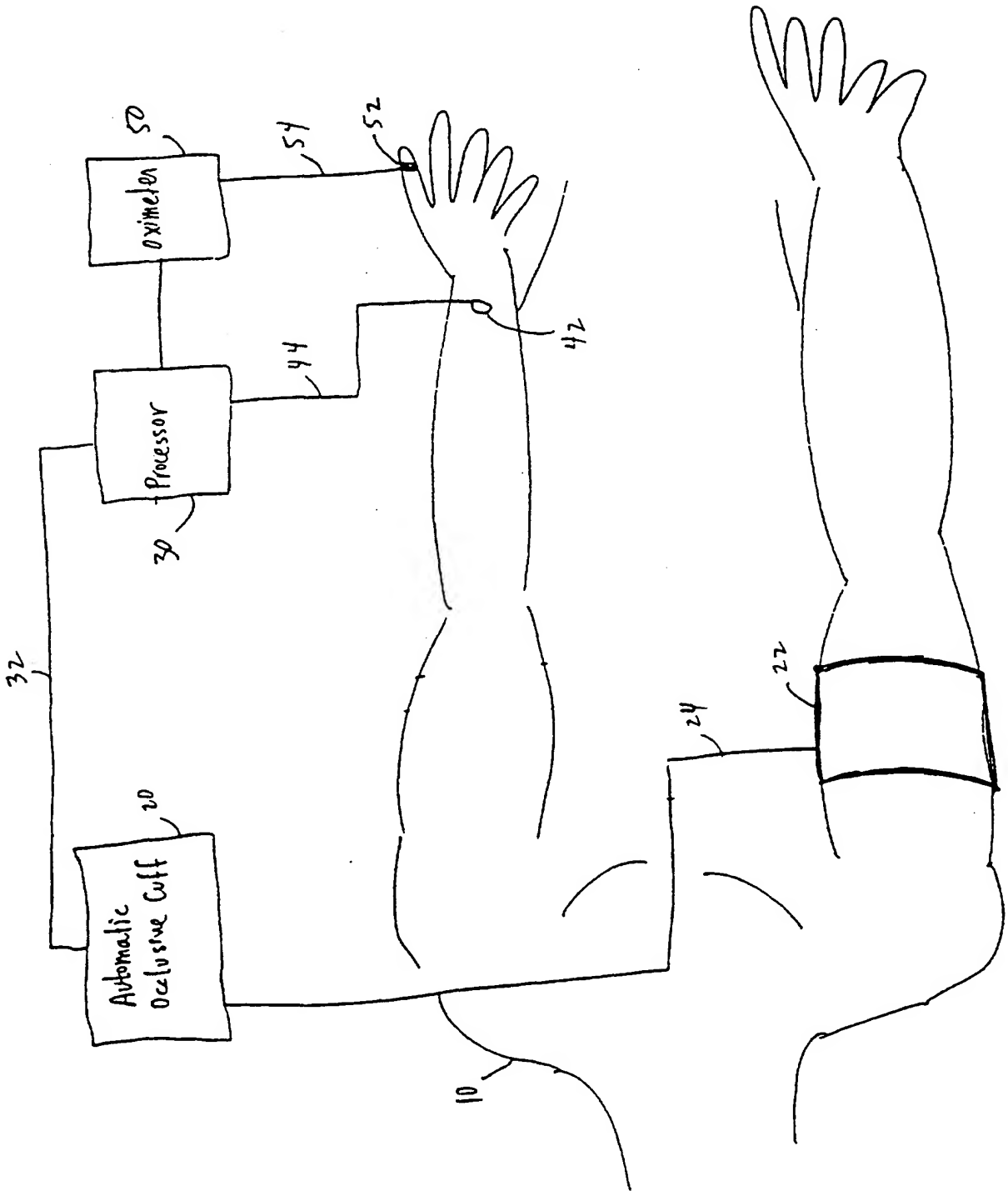
Oximeter
50
54
52
42
44
Processor
30
32
Automatic
Occlusive Cuff
20
10
24
22

FIG 6

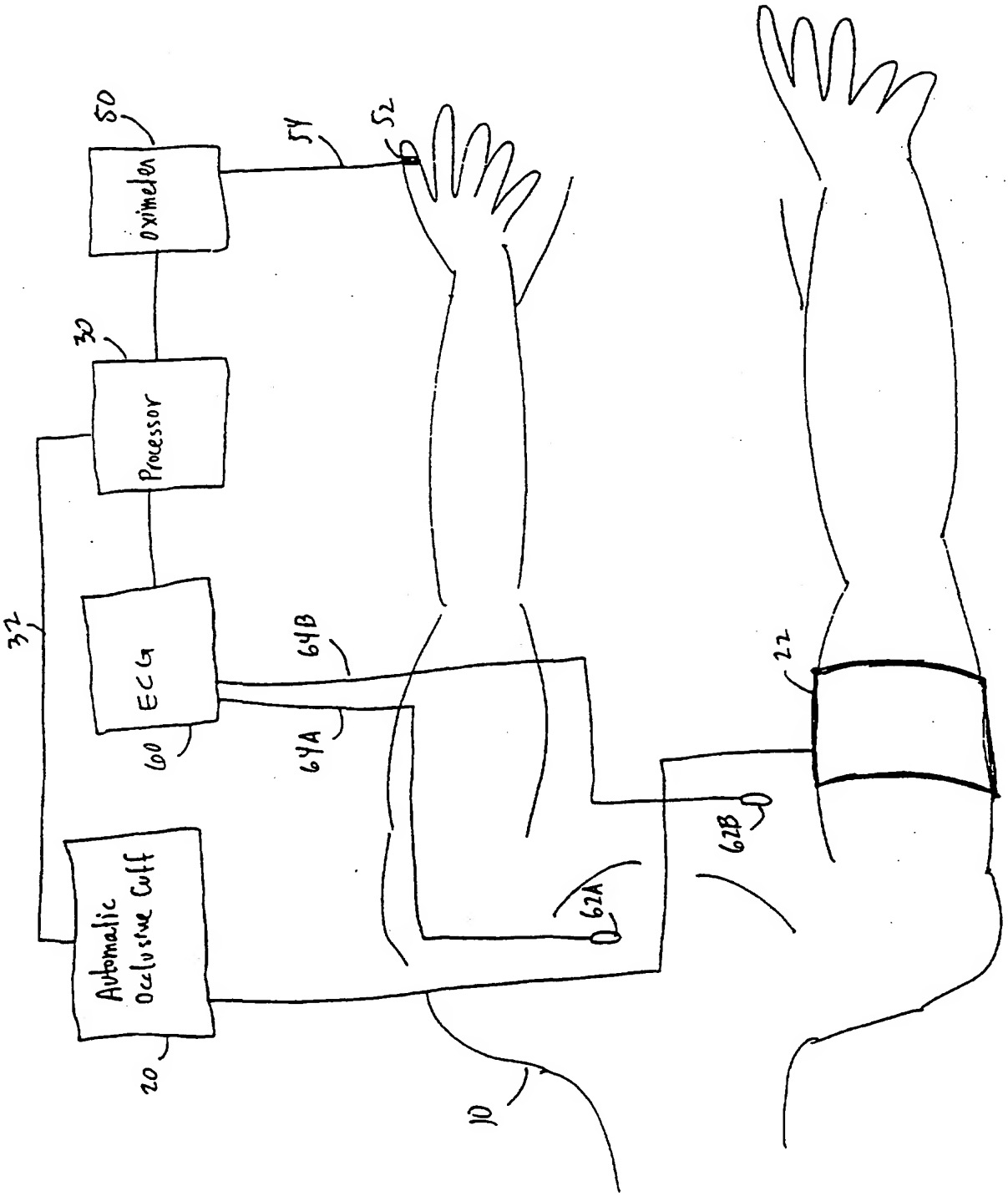
50
Oximeter
54
52
30
Processor
32
ECG
60
64B
64A
Automatic Occlusive Cuff
20
10
22
62B
62A

Fig 7

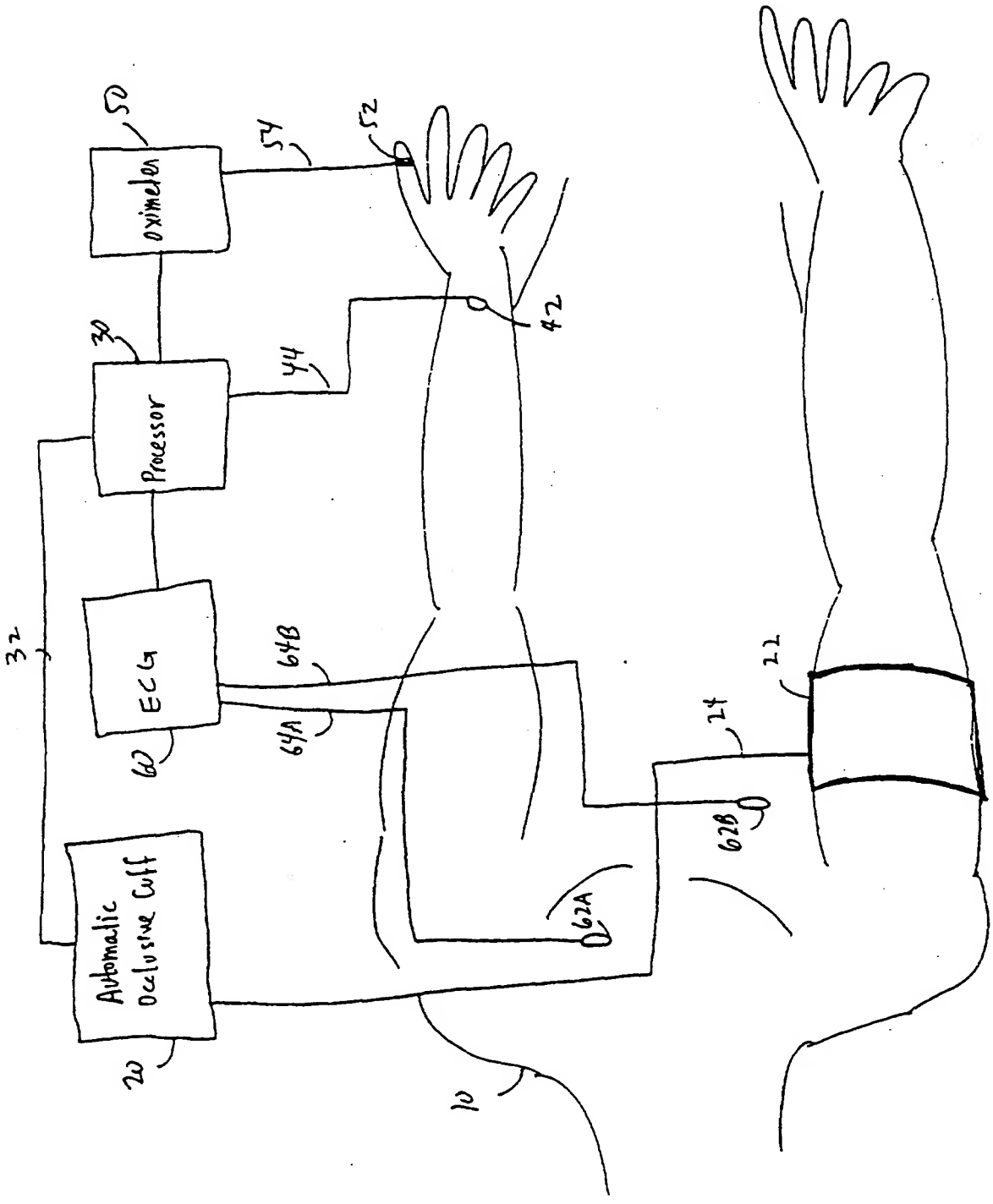
50
oximeter
54
52
42
30
Processor
44
32
ECG
64B
64A
60
Automatic
Occlusive Cuff
20
10
62A
62B
24
22

FIG 8

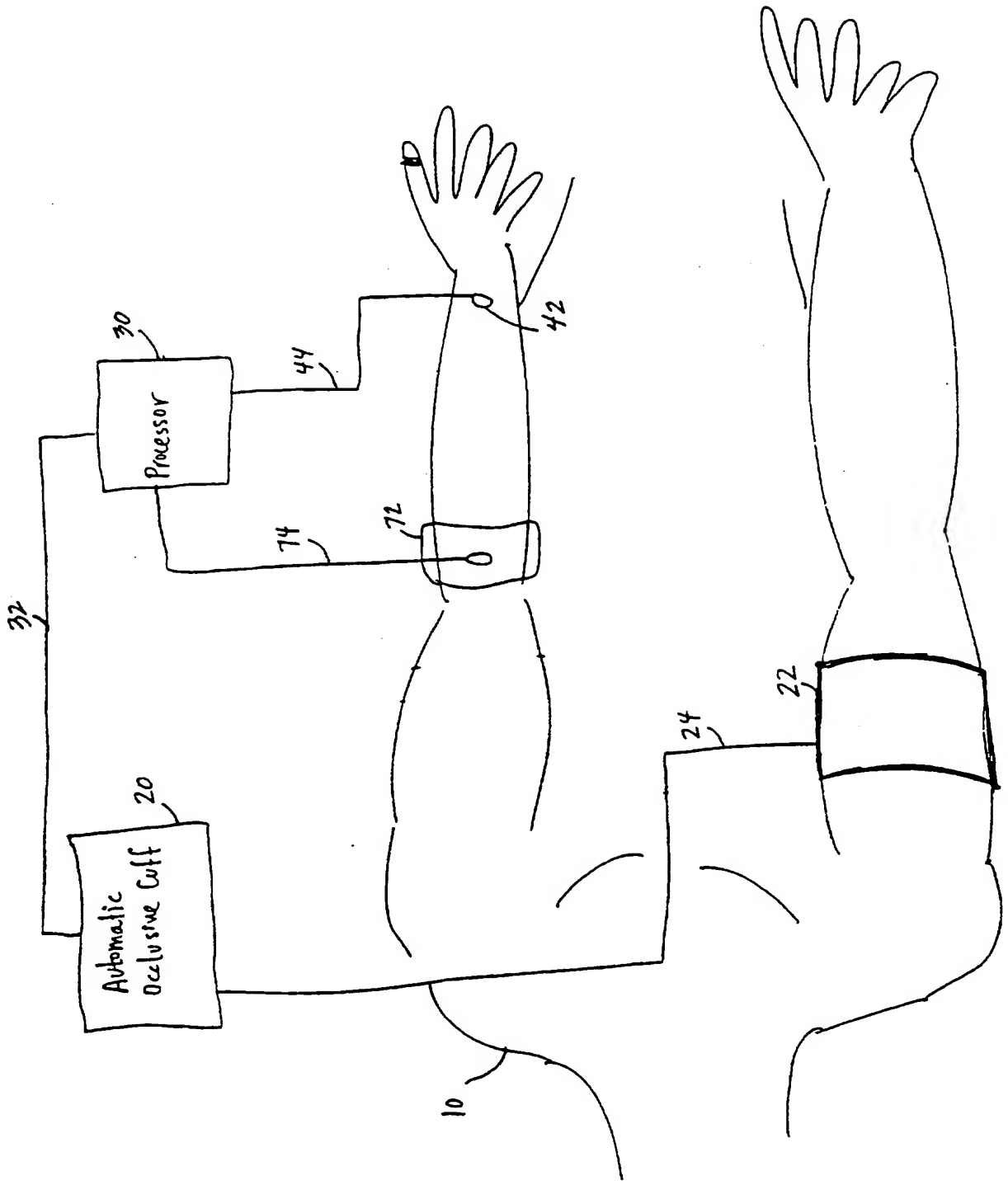
30
Processor
44
42
74
72
32
20
Automatic
Occlusive Cuff
10
22
24

FIG 9

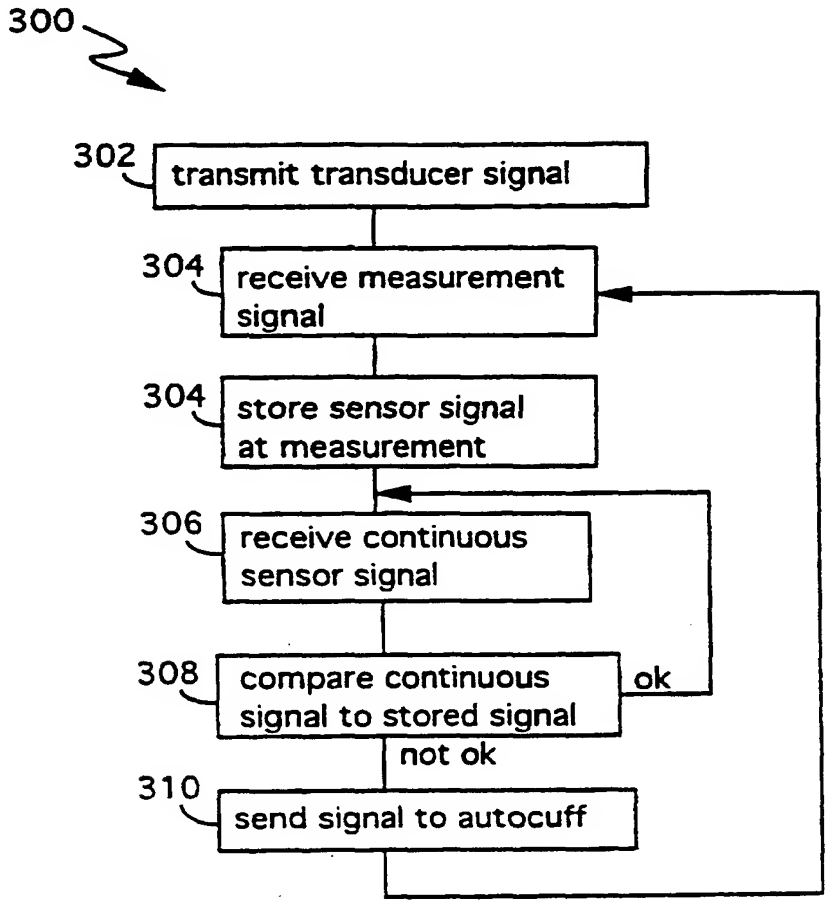

Figure 10

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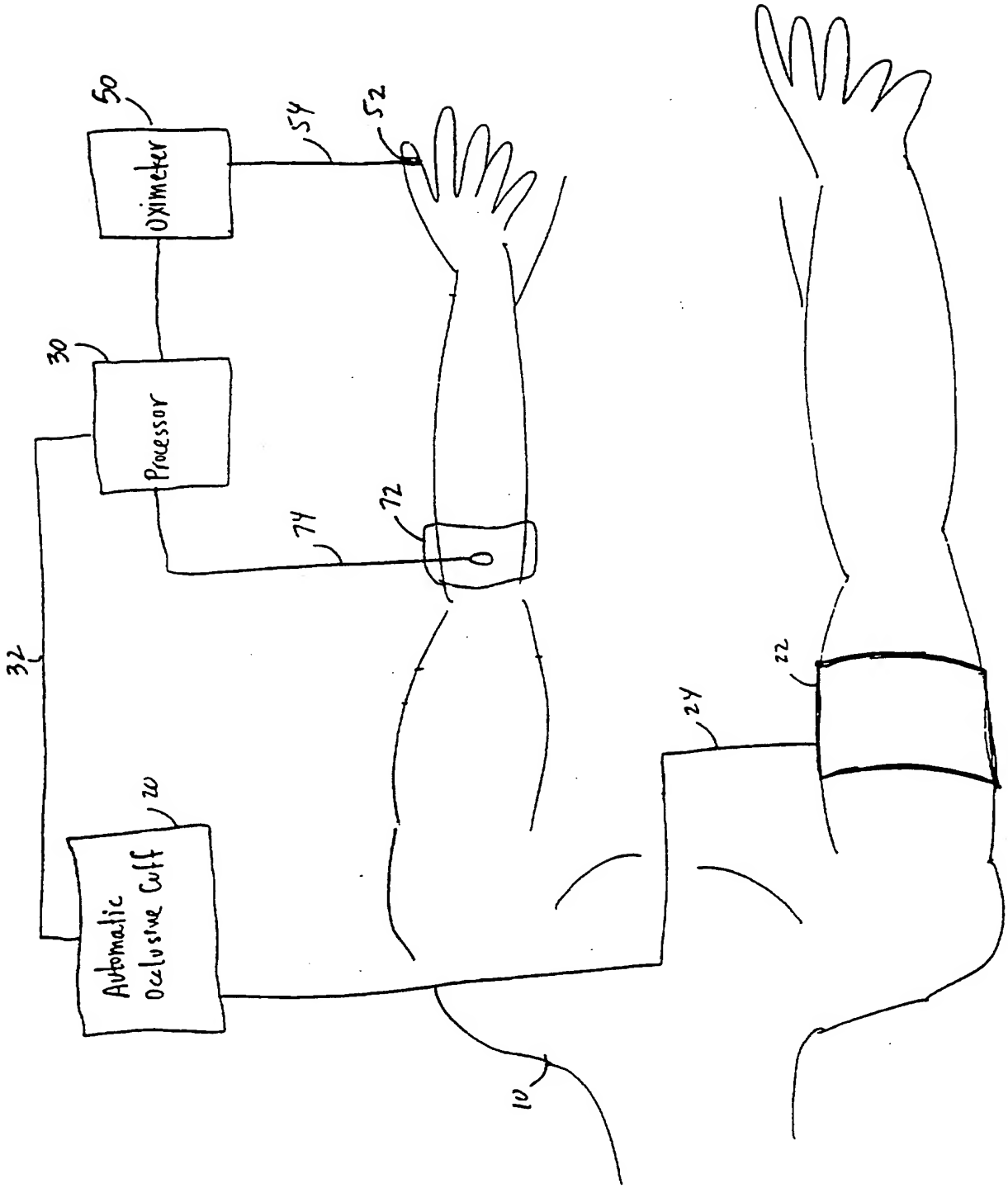
50
Oximeter
54
52
30
Processor
74
72
32
20
Automatic
Occlusive Cuff
10
24
22

FIG 11

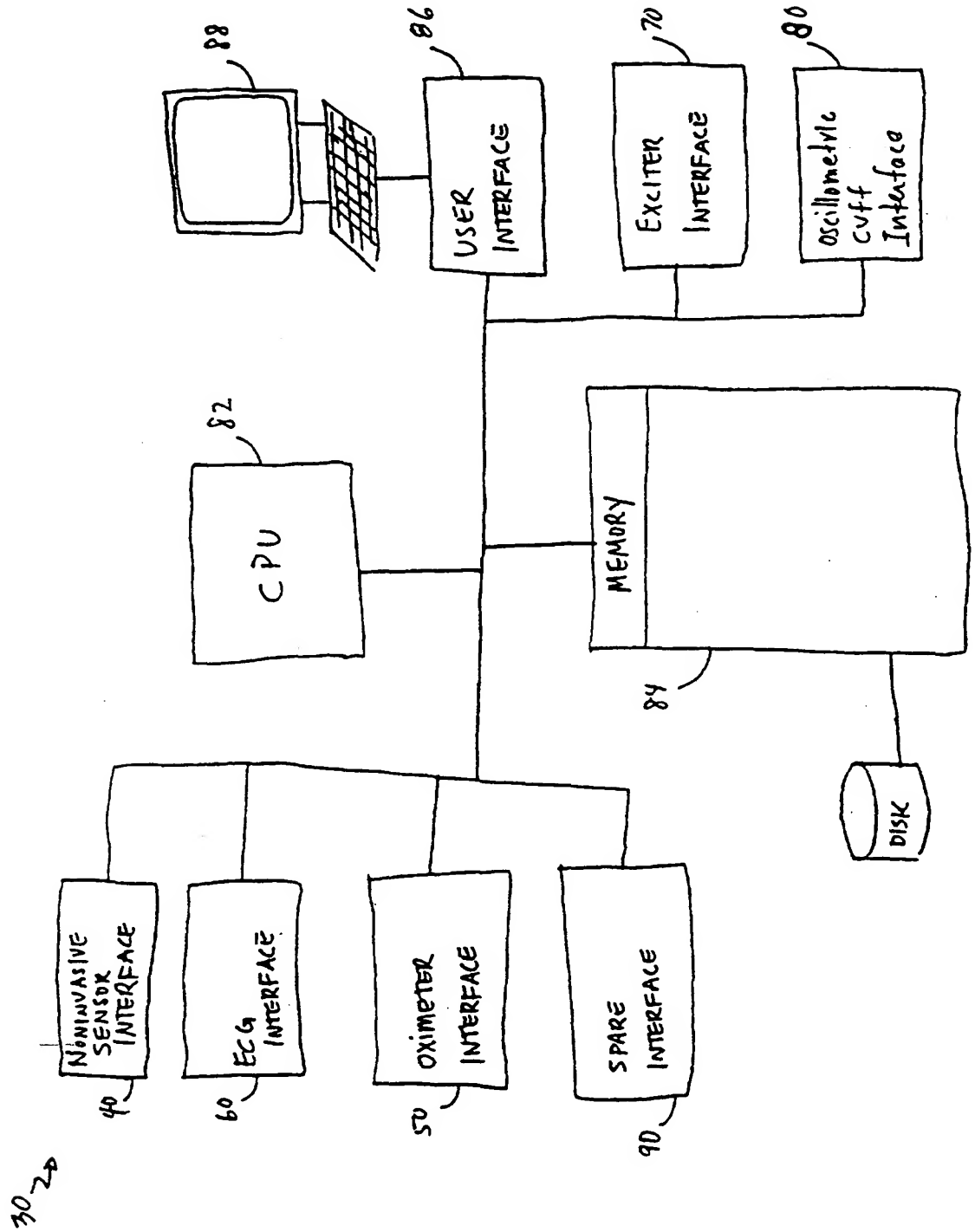
88
86
USER INTERFACE
70
EXCITER INTERFACE
80
Oscillometric cuff Interface
82
CPU
MEMORY
84
DISK
NONINVASIVE SENSOR INTERFACE
40
ECG INTERFACE
60
OXIMETER INTERFACE
50
SPARE INTERFACE
90
30 24

FIG 12

INTERNATIONAL SEARCH REPORT

International applicati n No.
PCT/US95/12452

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 05/00
US CL :128/668;
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/667, 668, 670, 672, 677-683, 687-694, 748

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Categ ry*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US, A, 5,111,817 (CLARK ET AL.) 12 May 1992, see entire document.	1-4, 12--20 --- 5-11, 21-32
A	US, A, 5,237,997 (GRUEBEL ET AL.) 24 August 1993, see entire document.	1-32.
A	US, A, 5,241,964 (McQUILKEN) 07 September 1993, see entire document.	1-32
A	US, A, 5,309,916 (Hatschek) 10 May 1994, see entire document.	1-32

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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Date of th actual completion of the international search
20 NOVEMBER 1995

Date of mailing f the international search report
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INTERNATIONAL SEARCH REPORT

International application N .
PCT/US95/12452

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation f document, with indication, where appropriate, of the relevant passages	Relevant to laim N .
X --- A	US, A, 5,279,303 (KAWAMURA ET AL.) 18 January 1994, see entire document.	1-3, 5, 12-19, 21 --- 4, 6-11, 20, 22-32.

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CORRECTED VERSION*

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08/322,261 13 October 1994 (13.10.94) US

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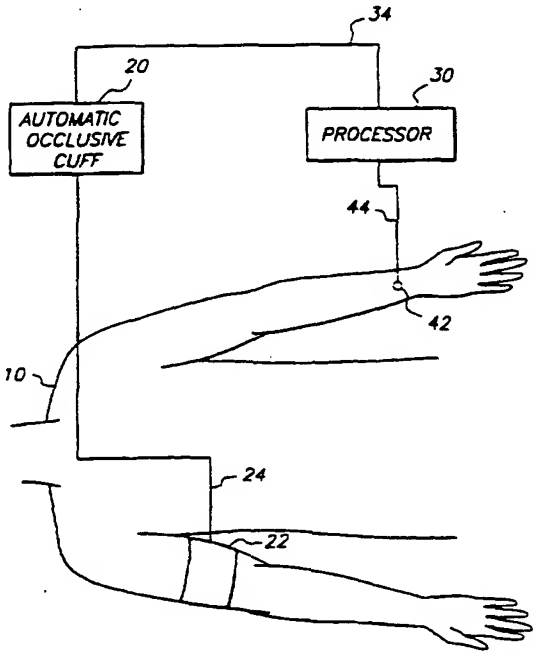
Published
With international search report.

(54) Title: AUTOMATICALLY ACTIVATED BLOOD PRESSURE MEASUREMENT DEVICE



(57) Abstract

A monitor for activating a sphygmomanometer (20, 22) attached to a patient includes a sensor (42, 52, 62A, 62B) to generate a sensor signal indicative f a physi logical parameter. The sensor (42, 52, 62A, 62B) can be, for example, a non-invasive sensor (42, 52, 62A, 62B) that generates a signal responsive to blood pressure. The monitor also has a processor (30) coupled to the sensor (42, 52, 62A, 62B) and to the sphygmomanometer (20, 22). The processor (30) is configured to process the sensor signal and to send a signal to activate the sphygmomanometer (20, 22) when the sensor signal meets predetermined criteria.

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SDOCID: <WO 9611625A1 IA>

AUTOMATICALLY ACTIVATED BLOOD PRESSURE MEASUREMENT DEVICE

Related Applications

This patent application is a continuation-in-part of Caro et al., U.S. Patent Application Ser. No. 08/228,213 filed April 15, 1994.

Field of the Invention

The present invention relates to an apparatus and method for automatically activating a blood pressure measurement device depending on a variety of sensed physiological parameters including a patient's blood pressure and other clinically important parameters.

Background of the Invention

Blood pressure is the force within the arterial system of an individual that ensures the flow of blood and delivery of oxygen and nutrients to the tissue. Prolonged reduction or loss of pressure severely limits the amount of tissue perfusion and could therefore result in damage to or even death of the tissue. Although some tissues can tolerate hypoperfusion for long periods of time, the brain, heart and kidneys are very sensitive to a reduction in blood flow. Thus, during and after surgery, blood pressure is a frequently monitored vital sign. Blood pressure is affected, during and after surgery, by the type of surgery and physiological factors such as the body's reaction to the surgery. Mor over, blood pressure

is manipulated and controlled, during and after surgery, using various m dications. Often, these physiological factors and the given medications can result in a situation of rapidly changing blood pressure requiring immediate blood pressure measurement, and corrective action.

Because of changes in the patient's blood pressure, constant monitoring is important. The traditional method of measuring blood pressure is with a stethoscope, occlusive cuff and pressure manometer. However, this technique is slow, subjective in nature, requires the intervention of a skilled clinician and does not provide timely readings frequently required in critical situations.

For these reasons, two methods of measuring blood pressure have been developed: noninvasive, intermittent methods that use an automated sphygmomanometer or cuff device such as an oscillometric cuff; and invasive, continuous (beat-to-beat) measurements that use a catheter and pressure transducer.

The cuff device typically requires 15 to 45 seconds to obtain a measurement, and should allow sufficient time for venous recovery. Too frequent cuff inflations over extended periods may result in ecchymosis and/or nerve damage in the area underlying the cuff. For this reason, periodic cuff measurements should not be taken more oft n than approximately once every 5 minutes. This is an inordinately long amount of time to wait for an updated pressure reading when fast acting medications are administered. The invasive method has inherent disadvantages including risk of embolization, infection, bleeding and vessel wall damage.

To address the need for continuous, noninvasive blood pressure measurement, several systems were developed. One system relies on blood pressure values in a patient's finger as indicative of the patient's central blood pressure. Another system uses two cuffs, one on each arm, to determine calibration readings and continuous readings

respectively. Another system transforms a time sampled blood pressure waveform into the frequency domain and determines blood pressure based on deviations of the fundamental frequency. Kaspari et al., U.S. Patent Application Ser. No. 08/177,448, filed January 5, 1994 provides examples of these systems.

Objects and Summary of the Invention

The present invention describes an apparatus and method for automatically activating a sphygmomanometer depending on a variety of parameters including a patient's blood pressure and other clinically important parameters.

An object of the present invention is to continuously monitor a sensor signal that is responsive to changes in the patient's blood pressure. A related object is to activate a cuff device when the sensor signal meets predetermined criteria.

Another object of the present invention is to induce a perturbation into a patient's blood or blood vessel and to continuously monitor a sensor signal that is responsive to changes in the patient's blood pressure. A related object is to activate a cuff device when the sensor signal meets predetermined criteria.

A monitor for activating a sphygmomanometer attach d to a patient includes a sensor attached to the patient to generate a sensor signal representative of a physiological parameter. This sensor can be, for example, a noninvasive sensor that generates a signal responsive to blood pressure. The monitor also has a processor coupled to the sensor and to the sphygmomanometer. The processor is configured to process the sensor signal and to send a signal to activate the sphygmomanometer when the sensor signal meets predetermined criteria.

In operation, the monitor initially activates the sphygmomanometer to obtain a blood pressure measurement. Thereafter, the sphygmomanometer is activated manually by a doctor or nurse, automatically at predetermined time intervals, or when the processor determines that the

DOCID: <WO___9611625A1_IA>

sensor signal indicates that the patient's blood pressure is sufficiently different from that previously m asured.

Brief Description of the Figures

Figure 1 depicts a first embodiment of the present invention attached to a patient;

Figure 2 depicts a flowchart showing the procedures involved in monitoring the patient for the first embodiment;

Figure 3 depicts a second embodiment of the present invention attached to a patient;

Figure 4 depicts a third embodiment of the present invention attached to a patient;

Figure 5 depicts a flowchart showing the procedures involved in monitoring the patient for the third embodiment;

Figure 6 depicts a fourth embodiment of the present invention attached to a patient;

Figure 7 depicts a fifth embodiment of the present invention attached to a patient;

Figure 8 depicts a sixth embodiment of the present invention attached to a patient;

Figure 9 depicts a seventh embodiment of the present invention attached to a patient;

Figure 10 depicts a flowchart showing the procedures involved in monitoring the patient for the seventh embodiment;

Figure 11 depicts an eighth embodiment of the present invention attached to a patient; and

Figure 12 depicts a processor for monitoring the patient according to the present invention.

Detailed Description of the Preferred Embodiments

The embodiments described operate by sensing specific physiological parameters to automatically activate a sphygmomanometer. However, it should be understood that the present invention is directed toward a device that operates by sensing any of a plurality of physiological

parameters to detect a change in the patient's blood pressure and to activate a blood pressure measuring device. In this context, the sphygmomanometer of the preferred embodiments can be substituted with any device capable of measuring blood pressure.

Those skilled in the art will appreciate that various changes and modifications can be made to the embodiments while remaining within the scope of the present invention. Moreover, currently pending patent applications incorporated herein by reference are Kaspari et al., U.S. Patent Application Ser. No. 08/177,448 filed January 5, 1994, and Caro et al., U.S. Patent Application Ser. No. 08/228,213 filed April 15, 1994.

A first embodiment is explained with reference to Figures 1 and 2. A patient 10 is shown with an sphygmomanometer 20, 22, attached to the upper arm. The sphygmomanometer includes the control unit 20 and the cuff 22. The cuff 22 is attached to the control unit 20 via a trunk 24 that controls the inflation of the cuff 22 and receives signals from the cuff regarding the systolic and diastolic blood pressure. This type of automatic cuff is known in the art, however, an explanation of the operation is given for clarity.

In operation, the cuff 22 is attached to one of the patient's limbs, such as an arm or leg. It is even possible that the cuff be attached to the same limb as that to which any sensor is attached. The cuff is first pressurized to abate the blood flow in the limb. Then, as the pressure is slowly reduced, a transducer senses when the blood flow begins and this pressure is recorded as the systolic pressure. As the pressure is further reduced, the transducer similarly detects when full blood flow is restored and this pressure is recorded as the diastolic pressure. The signals representing pressure are delivered, via trunk 24 to control unit 20.

A processor 30 is coupled to the sphygmomanometer control unit 20 via cable 34. The processor 30 receives information regarding the patient's blood pressure from

the control unit 20, and can activate the control unit 20 via the cable 34. The processor 30 is also coupled to a noninvasive sensor 42 via cable 44. The sensor 42 is a piezoelectric sensor that generates a signal related to the blood pressure at the sensor site. In Figure 1, the sensor 42 is shown attached over the radial artery, but can be placed over any artery that is close to the skin surface. The sensor 42 generates a signal that is communicated to the processor 30 via cable 44.

A user sets a periodic measurement interval time for the sphygmomanometer, which can range from 2-60 minutes or longer. Then, the user initializes the processor 30 which begins the procedural flowchart 100 with step 102 by initializing the processor input signals. The processor 30 sends an initialization signal to the cuff control unit 20 to obtain a blood pressure measurement. The control unit 20, in turn, activates the cuff 22 and determines the blood pressure of the patient 10. Simultaneously, in step 104, the processor 30 receives the sensor signal from the sensor 42 and stores a record of the signal during measurement. Alternatively the processor stores a record of the sensor signal just before measurement or just after measurement.

During the time between measurements, in step 106, the processor 30 then receives a continuous signal from the sensor 42. The processor 30, in step 108, continuously compares the continuous sensor signal to the stored sensor signal taken during measurement. This comparison can include a comparison of periodicity, peak value, low value, waveshape, or any other factors. If, for example, waveshape is used, the processor 30 can compare the relative start time, peak time and ending time against the stored signal. If the chosen parameters conform with the testing criteria, or are within a defined bounds, then the processor continues to receive the continuous sensor signal and to compare it against the stored signal. However, if one or more of these parameters changes, the processor may determine that the

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patient's blood pressure has changed since the last measur ment and may move to step 110 where the proc ssor 30 sends a signal to the control unit 20 to perform a blood pressure measurement. This is the equivalent of an initial measurement as performed in step 102 and the iterative procedure begins again.

Figure 3 depicts a second embodiment using a photoplethysmograph. One type of photoplethysmograph, for example, is an oximeter control unit 50 coupled to an oximeter sensor 52 via cable 54. The oximeter sensor 52 performs a similar function to the noninvasive sensor 42 of the first embodiment by measuring the blood flow in a patient's extremity. The processor takes the oximeter sensor signal and performs the same procedure 100 to activate the sphygmomanometer control unit 20 as described in the first embodiment. Photoplethysmograph sensors are known in the art, and a good discussion of their functions is described in C.M. Alexander, Principles of Pulse Oximetry: Theoretical and Practical Considerations, Anesth Analg vol. 68 p. 368-376 (International Anesthesia Research Society 1989). In general, they shine light through an appendage, such as a finger or earlobe, and measure the attenuation of the light. The attenuation of the light has a direct relationship to the amount of oxygen in the blood, and the amount of oxygen in the blood has a direct relationship to the patient's pulse.

A third embodiment is described with reference to Figures 4 and 5. A sphygmomanometer is attached to th patient similar to the first embodiment. In this embodiment, however, the processor 30 is coupled to two sensors. The processor 30 is coupled to a noninvasive arterial sensor 42 and an electrocardiogram (ECG) unit 60, which is attached to sensor 62A and 62B via cables 64A and 64B respectively. The purpose of this configuration is to measure the time difference of arrival of the pulse at different points of the body.

A known relationship exists between pressure and velocity of a pulse. This is defined by equation 1:

$$V \propto A + BP$$

where V is velocity, A and B are constants and P is pressure. The velocity versus pressure curve is monotonic but not necessarily linear. However, the curve can be represented as piecewise linear over a range sufficient to be used in the present invention. The times of arrival at the first sensor (T_1) and at the second sensor (T_2) are subtracted to determine a time difference of arrival (TDOA). This equation is used to determine a change in blood pressure over time. Many factors are involved in the relationship between the TDOA and pressure, such as heart strength, arterial flexibility, length between the sensors and others, and they vary from patient to patient. However, since for any single patient the variables remain substantially constant for all practical purposes during the monitoring time, these factors do not need to be quantified for each patient.

Turning to the flowchart 200, the measurement step 202 is performed by activating the cuff control unit 20 and then in step 204a and 204b by receiving the ECG signal from the ECG unit 60 and receiving the noninvasive sensor signal from the noninvasive sensor 42. Then the time difference is calculated by the processor 30 in step 206, and that value is stored.

The processor continuously receives the sensor signals from the ECG unit 60 and the noninvasive sensor 42 in step 208a and 208b, and continuously determines the TDOA in step 210. A comparison of the continuous TDOA and the stored TDOA is performed in step 212. If, according the equation 1, a change in TDOA is within predetermined bounds, then the continuous monitoring continues. An example of criteria used to determine if the TDOA is within bounds is a TDOA change of 10%, a change of 20%, or a change of 30% or more. The specific criteria can be altered and may differ depending on many factors including

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the patient's health, the type of surgery, the type of anesthetic and other factors.

If the processor determines that a change occurs outside a predetermined bound, then, in step 214, the processor sends a signal to the control unit 20 to initiate a new measurement. Execution of the measurement returns the processing to step 202.

Figure 6 depicts a fourth embodiment similar to the third embodiment. The ECG unit 60 is replaced with a photoplethysmograph, such as an oximeter unit 50. The procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 7 depicts a fifth embodiment similar to the third embodiment. The noninvasive sensor 40 is replac d with a photoplethysmograph, such as an oximeter unit 50. The procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 8 depicts a sixth embodiment similar to the third embodiment, but using an additional third sensor. The addition of the third sensor can be used, for example, to refine the time difference between pulse arrival at the first and second, second and third, and first and third sensors. Again, the procedures performed with respect to the sensors are identical to those performed with respect to the third embodiment and are depicted in flowchart 200.

Figure 9 depicts a seventh embodiment that uses an induced perturbation to determine whether a change in blood pressure occurs. This embodiment uses the time delay between a known exciter waveform and a sensor to monitor a change in the patient's blood pressure. An exciter 72 is attached to one of the patient's limbs, such as to the forearm above the radial artery. The exciter 72 is a device for inducing a m chanical perturbation of the patient's body tissue, and can be a device such as an inflatable bag fixed in place near an accessible artery by a holddown device such as a buckle, adhesive strap or

SNSDOCID: <WO 9611625A1 IA>

other device. Moreover, the exciter is controlled by the processor 30 via air tube 74. Alternatively, the exciter can be an electro-mechanical device such as a piezoelectric exciter or a solenoid exciter or other similar device, where the air tube is replaced with a wire.

The perturbation excites the tissue and blood vessel below the exciter and causes a perturbation waveform to radiate within the patient's body, at least a portion of which travels in the arterial blood. Experiments conducted to determine a range of satisfactory perturbation frequencies found that the range of 20-600Hz works well. It is anticipated that frequencies of lesser than 20Hz and greater than 600Hz will also work well, and it is intended that this specification cover all frequencies insofar as the present invention is novel.

Figure 9 further shows a noninvasive sensor 42 placed at a distance from the exciter on the patient's wrist. The noninvasive sensor is connected to the processor 30 via cable 44. As is shown, the sensor is positioned over the radial artery and it is responsive to pressure variations therein. As the pressure increases, the piezoelectric material deforms and generates a signal corresponding to the deformation.

Since a known relationship exists between blood pressure and exciter waveform velocity, a deviation in the time of transit indicates a change in blood pressure. Also, at a given frequency many other relationships are known: a relationship exists between velocity and wavelength, the greater the velocity the longer the wavelength; and a relationship exists between wavelength and phase, a change in wavelength will result in a proportional change in phase. As a result, the exciter signal is continuously measured by the sensor and a comparison is continuously made against the sensor signal stored at measurement to determine if the patient's blood pressure changes.

Referring to Figure 10, a flow chart 300 shows the procedure used to determine whether the patient's blood pressure changes. First, the exciter signal is generated by the processor and transmitted to the exciter. A measurement step 302 activates the sphygmomanometer control unit 20 and determines the patient's blood pressure, as described above. Then the processor stores the sensor signal at measurement in step 304. In step 306, the processor continuously receives the sensor signal.

In step 308, the processor then continuously compares the continuous sensor signal to the sensor signal stored at measurement to determine if the blood pressure changes. This determination can be based on many factors including the time since the last measurement, whether the linearity of the velocity/pressure curve is outside of a reliable range, determination by medical personnel that a new measurement is desired or other factors. As an example of these factors, the embodiments provide user settable measurement time intervals of 2-60 minutes or more. For a periodic exciter waveform a known relationship exits between the phase of the continuous sensor signal and the blood pressure. This is represented by equation 2:

$$\Phi \propto C + DP$$

where Φ is phase, C and D are constants and P is pressure. The phase change as related to blood pressure also depends on the wavelength and frequency of the exciter wave, referring to the first equation which relates pressure and velocity. Moreover, the phase versus pressure curve is not necessarily linear, but the curve can be represented as piecewise linear over a range sufficient to be used in the present invention. Therefore, in step 308, the processor determines whether the sensor signal is valid within a predetermined phase change and within a predetermined piecewise linear region of the phase/pressure curve. If the continuous sensor signal is within bounds, the processing continues to step 306.

Step 310 is performed when step 308 determines that th prior m asur ment is no longer reliable as described above, such as the periodic time is expired or the patient's blood pressure changes beyond a predetermined bound. After step 310 is performed, the processing returns to step 304.

Figure 11 depicts an eighth embodiment showing the noninvasive sensor replaced by an oximeter sensor 52. This embodiment is similar to the seventh embodiment and the flowchart 300 is applicable to show the procedure for employing this embodiment.

With regard to all the embodiments, Figure 12 depicts a processor 30 that can perform the functions of receiving the sensor signals and processing the sensor signals to determine when to activate the sphygmomanometer. The processor includes a noninvasive sensor interface 40 to receive the noninvasive sensor signal. An oximeter interface 50 is for receiving the oximeter sensor signal. An ECG interface 60 is for receiving the ECG sensor signal, which can include a plurality of inputs for a plurality of ECG sensors. An exciter interface 70 is for sending a signal to the exciter to cause a perturbation wave in the patient. A sphygmomanometer interface 80 is to receive readings from the cuff transducers and to activate the cuff when required. And, a spare interfac 90 is included to receive or transmit signals to other sensors or processors.

All the device interfaces are coupled to a central processing unit (CPU) 82 and a memory 84. Moreover, a user interface 86 is included to receive input from a user and to display any required information to the user on a display 88. One skilled in the art will recognize that the processor 30 is a general purpose type computer specially configured with interfaces for required device interfaces -- depending on the embodiment -- and programmed to perform the procedures set forth in the present invention -- again, depending on the embodiment.

Alternately, processor 30 can be specially designed to perform the functions described in the invention.

VARIATIONS ON THE DISCLOSED EMBODIMENTS

Various noninvasive sensors have been developed for sensing a variety of physiological parameters. These sensor types include piezoelectric, piezoresistive, impedance plethysmograph, photoplethysmograph, various types of strain gauges, air cuffs, tonometry, conductivity, resistivity and other devices. Also, many invasive sensors can be used with the present invention, if so desired. The present invention can use any sensor that provides a waveform related to the physiological parameter of interest.

Having disclosed a preferred embodiment and the best mode, modifications and variations may be made to the disclosed embodiments without departing from the subject and spirit of the invention as defined by the following claims.

CLAIMS

What is claimed is:

1. A monitor for indicating a change in a patient's blood pressure, comprising:

a first sensor attached to the patient to generate a first signal representative of a physiological parameter of the patient; and

a processor coupled to said first sensor and configured to process said first signal and to generate a signal indicating a change in the patient's blood pressure when said first signal meets predetermined criteria.

2. The monitor of claim 1, wherein:

said predetermined criteria includes waveshape criteria.

3. The monitor of claim 1, wherein:

said first sensor is a noninvasive arterial sensor configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient.

4. The monitor of claim 1, wherein:

said first sensor is a photoplethysmograph sensor configured to generate said first signal responsive to a change in the volume of blood in an artery of the patient.

5. The monitor of claim 1, further comprising:

a sphygmomanometer attached to the patient and coupled to said processor; and

wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

6. The monitor of claim 1, further comprising:

a second sensor attached to the patient to generate a second signal representative of a second physiological parameter of the patient; and

wherein said processor is further coupled to said second sensor and further configured to process said

second signal and to generate a signal indicating a change in the patient's blood pressure when said first signal and said second signal meet predetermined criteria.

7. The monitor of claim 6, wherein:
said predetermined criteria includes time difference of arrival criteria.

8. The monitor of claim 6, wherein:
said first sensor is an ECG sensor configured to generate said first signal responsive to electrical impulses in the chest of the patient; and
said second sensor is a noninvasive arterial sensor configured to generate said second signal responsive to a change in arterial pressure in an artery of the patient.

9. The monitor of claim 6, wherein:
said first sensor is an ECG sensor configured to generate said first signal responsive to electrical impulses in the chest of the patient; and
said second sensor is a photoplethysmograph sensor configured to generate said second signal responsive to a change in the volume of blood in an artery of the patient.

10. The monitor of claim 6, wherein:
said first sensor is a noninvasive arterial sensor configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient; and
said second sensor is a photoplethysmograph sensor configured to generate said second signal responsive to a change in the volume of blood in an artery of the patient.

11. The monitor of claim 6, further comprising:
a sphygmomanometer attached to the patient and coupled to said processor; and
wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

ISDOCID: <WO 9611625A1 IA>

12. A monitor for indicating a change in a patient's blood pressure, comprising:

an exciter attached to the patient to generate a perturbation in said patient;

a sensor attached to the patient to generate a sensor signal representative of a physiological parameter of the patient; and

a processor coupled to said exciter and to said sensor and configured to process said sensor signal and to generate a signal indicating a change in the patient's blood pressure when said sensor signal meets predetermined criteria.

13. The monitor of claim 12, wherein:

said predetermined criteria includes phase change criteria.

14. The monitor of claim 12, wherein:

said sensor is a noninvasive arterial sensor configured to generate said first signal responsive to a change in arterial pressure in an artery of the patient.

15. The monitor of claim 12, wherein:

said sensor is a photoplethysmograph sensor configured to generate said first signal responsive to a change in the volume of blood in an artery of the patient.

16. The monitor of claim 12, further comprising:

a sphygmomanometer attached to the patient and coupled to said processor; and

wherein said signal indicating a change in the patient's blood pressure activates said sphygmomanometer.

17. A method of determining when a patient's blood pressure changes and generating a signal indicating a change in the patient's blood pressure, comprising the steps of:

sensing a first physiological parameter of the patient;

generating a first signal representative of the first physiological parameter of the patient;

processing the first signal; and

when said first signal meets predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

18. The method of claim 17, wherein:

said step of processing said first signal is performed by comparing said first signal to predetermined criteria including waveshape criteria.

19. The method of claim 17, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

20. The method of claim 17, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

21. The method of claim 17, further comprising the step of:

when the signal indicating a change in the patient's blood pressure is generated, activating a sphygmomanometer.

22. The method of claim 17, further comprising the steps of:

sensing a second physiological parameter of the patient;

generating a second signal representative of the second physiological parameter of the patient;

processing the second signal; and

when said first signal and said second signal meet predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

23. The method of claim 22, wherein:

said step of processing said first signal and said step of processing said second signal are performed by comparing said first signal and said second signal to predetermined criteria including time difference of arrival criteria.

24. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing the ECG of the patient; and

said step of sensing a second physiological paramet r of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

25. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing the ECG of the patient; and

said step of sensing a second physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

26. The method of claim 22, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient; and

said step of sensing a second physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

27. The method of claim 22, further comprising the step of:

when the signal indicating a change in the patient's blood pressure is generated, activating a sphygmomanometer.

28. A method of determining when a patient's blood pressure changes and generating a signal indicating a change in the patient's blood pressure, comprising the steps of:

generating a perturbation in the patient;

sensing a first physiological parameter of the patient;

generating a first signal representative of the first physiological parameter of the patient;

processing the first signal; and

when said first signal meets predetermined criteria, generating a signal indicating a change in the patient's blood pressure.

29. The method of claim 28, wherein:

said step of processing the first signal is performed by comparing said first signal to predetermined criteria including signal phase criteria.

30. The method of claim 28, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in arterial pressure in an artery of the patient.

31. The method of claim 28, wherein:

said step of sensing a first physiological parameter of the patient is performed by sensing a change in volume of blood in an artery of the patient.

32. The method of claim 28, further comprising the step of:

when the signal indicating a change in the patient's blood pressure is generated, activating a sphygmomanometer.

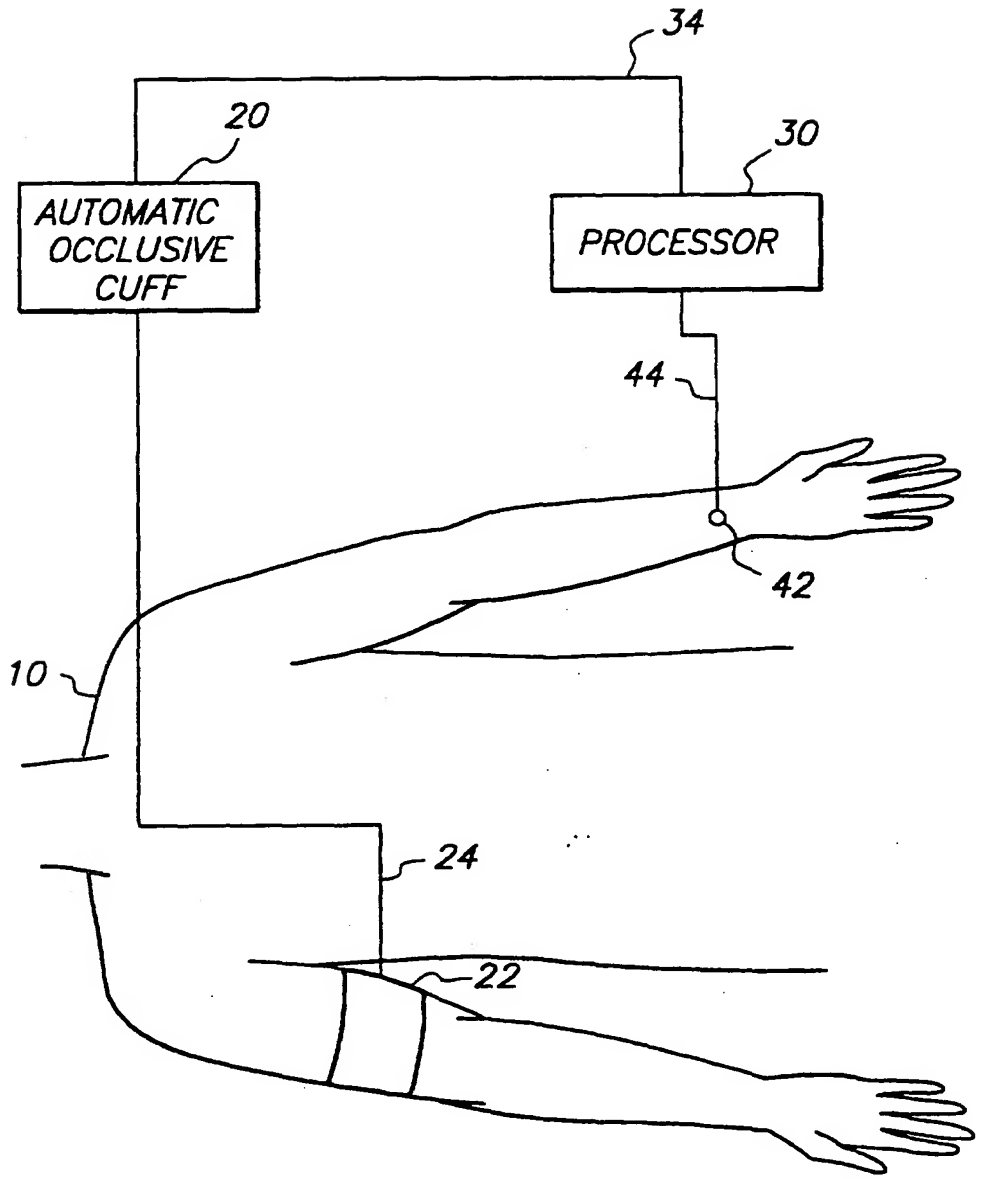
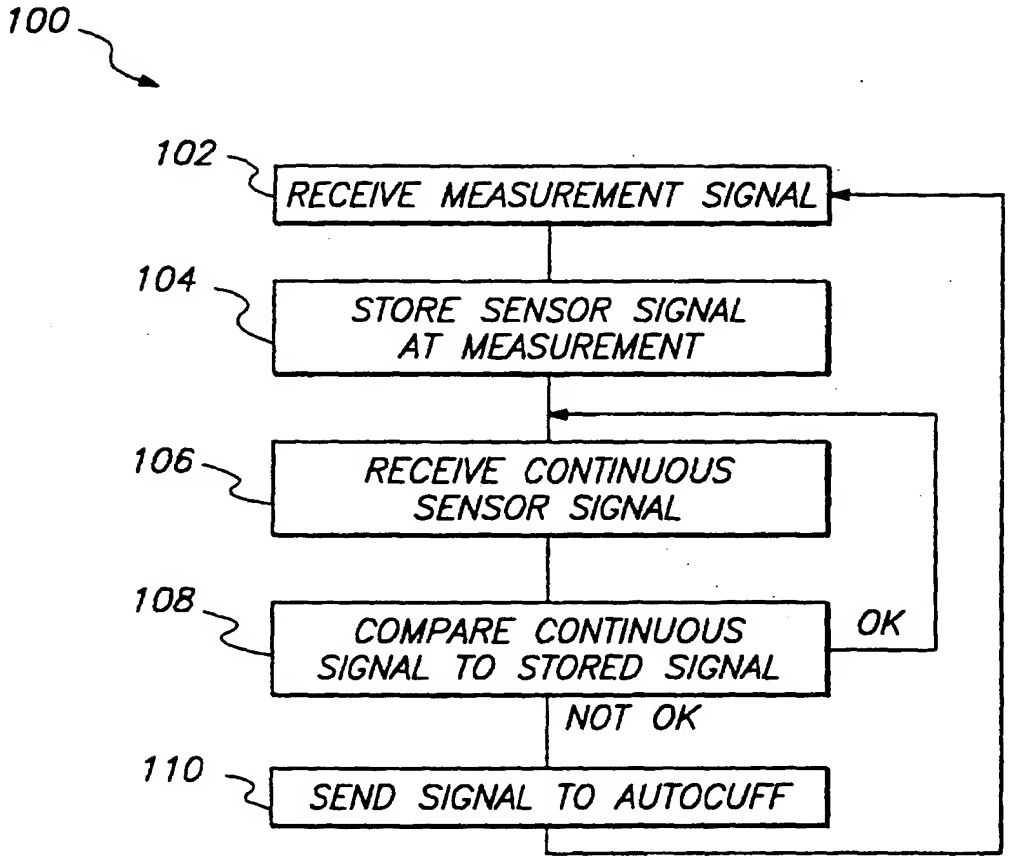


FIG. 1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RECEIVE MEASUREMENT SIGNAL
104
STORE SENSOR SIGNAL AT MEASUREMENT
106
RECEIVE CONTINUOUS SENSOR SIGNAL
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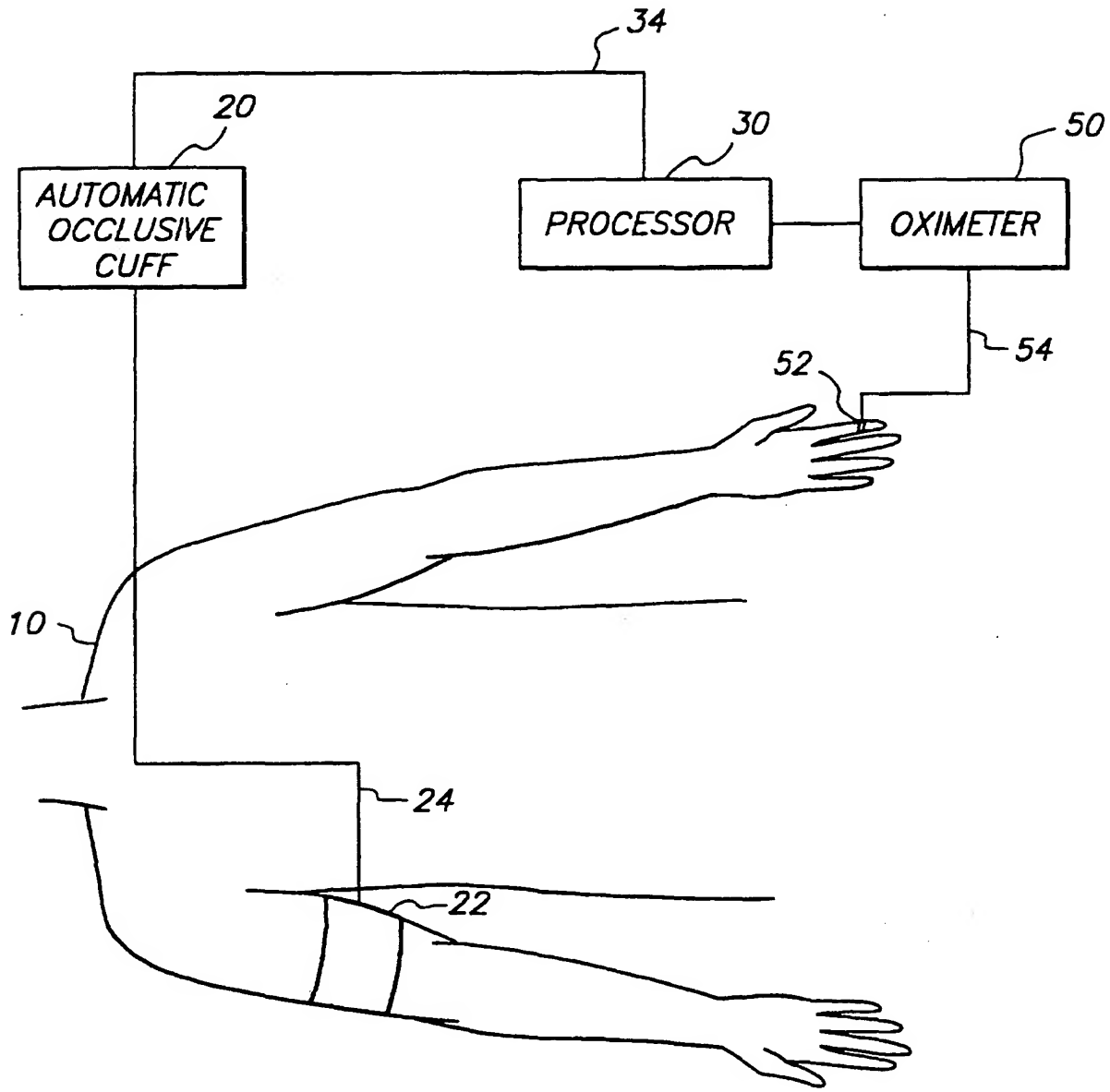
COMPARE CONTINUOUS SIGNAL TO STORED SIGNAL
OK
NOT OK
110
SEND SIGNAL TO AUTOCUFF

FIG. 2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PROCESSOR
OXIMETER
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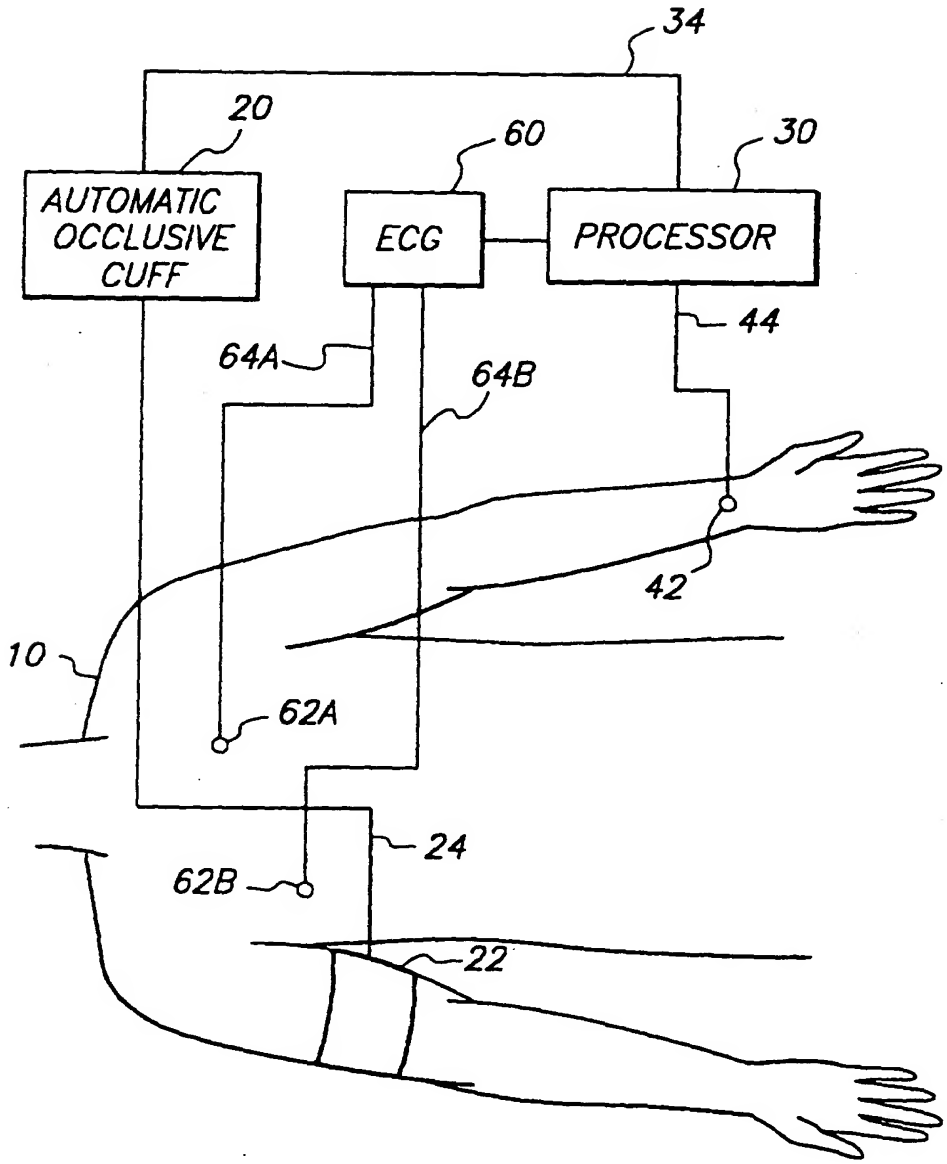
24
22

FIG. 3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60
30
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ECG
PROCESSOR
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64A
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42
10
62A
24
62B
22

FIG. 4

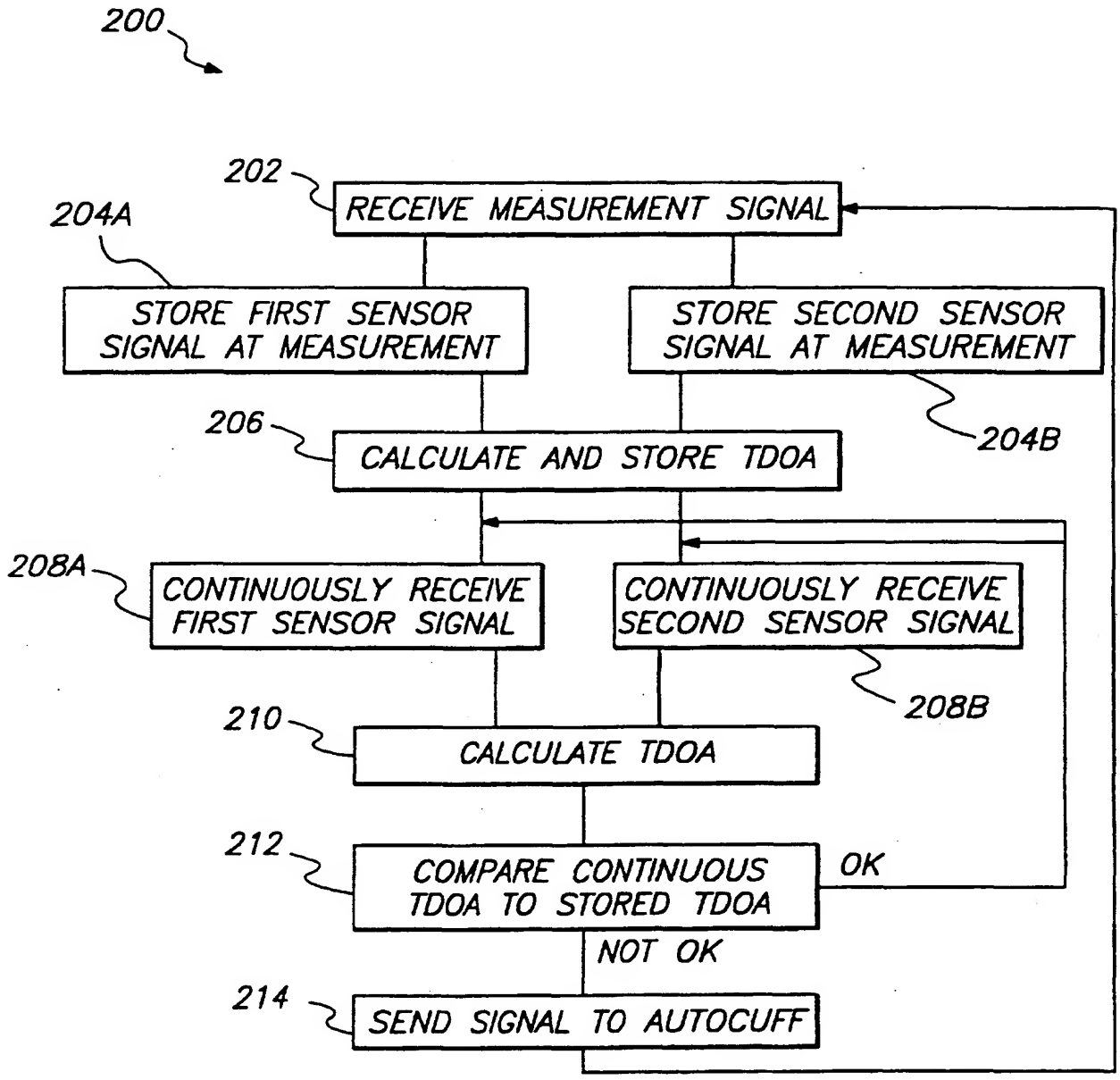
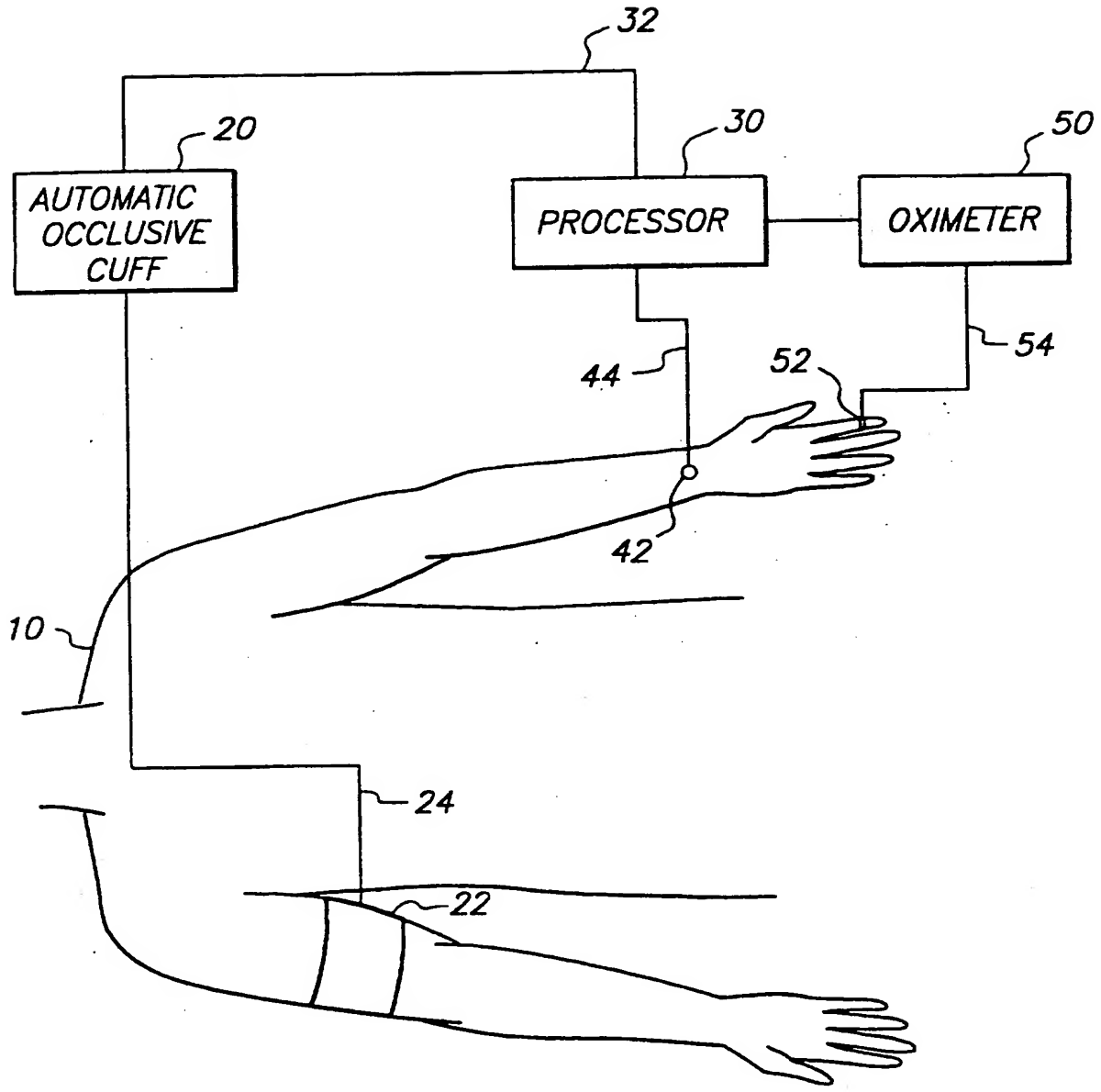


FIG. 5

SDOCID: <WO 9611625A1 IA>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30
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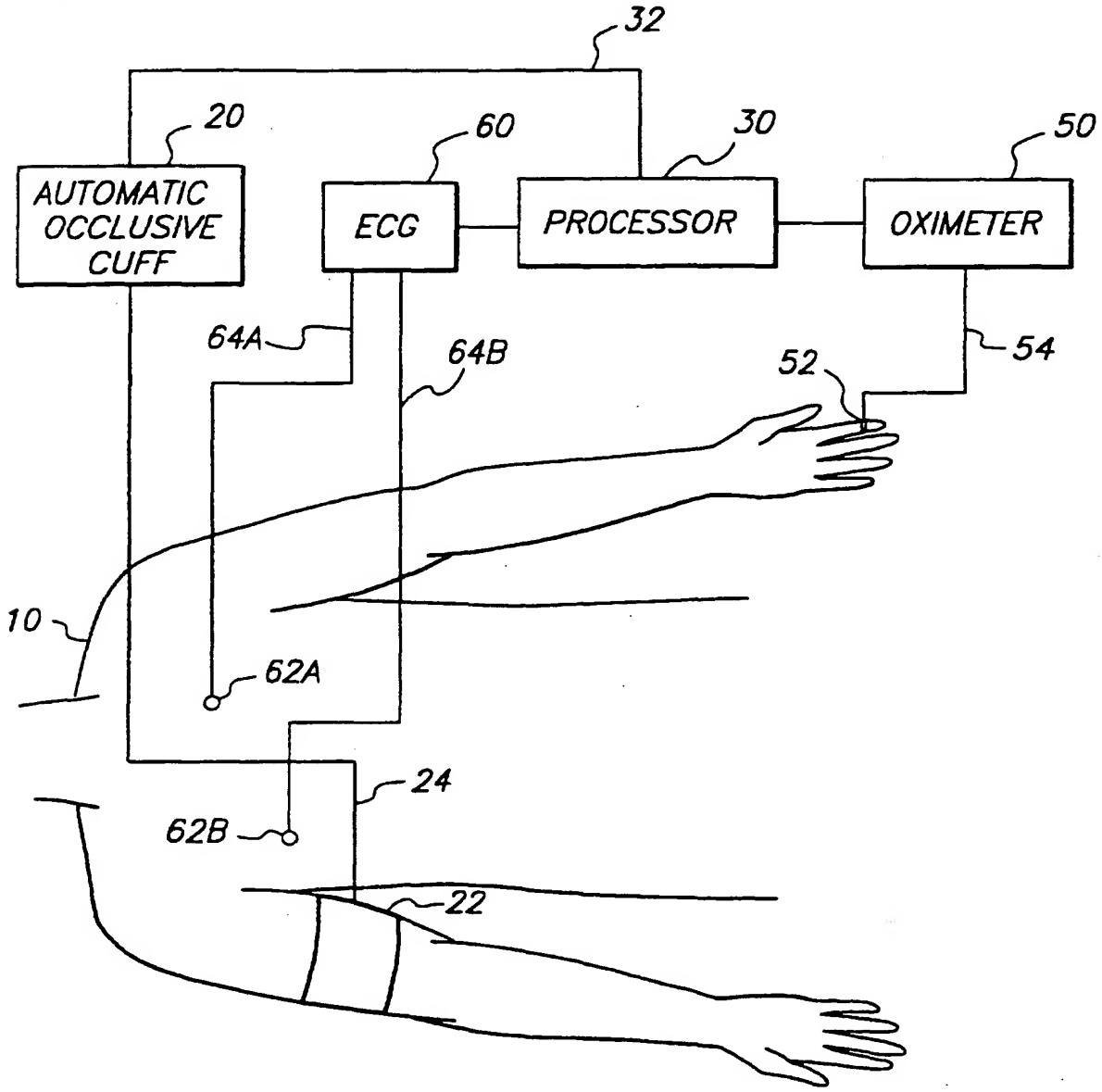
AUTOMATIC OCCLUSIVE CUFF
PROCESSOR
OXIMETER
44
52
54
42
10
24
22

FIG. 6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AUTOMATIC OCCLUSIVE CUFF
ECG
PROCESSOR
OXIMETER
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64B
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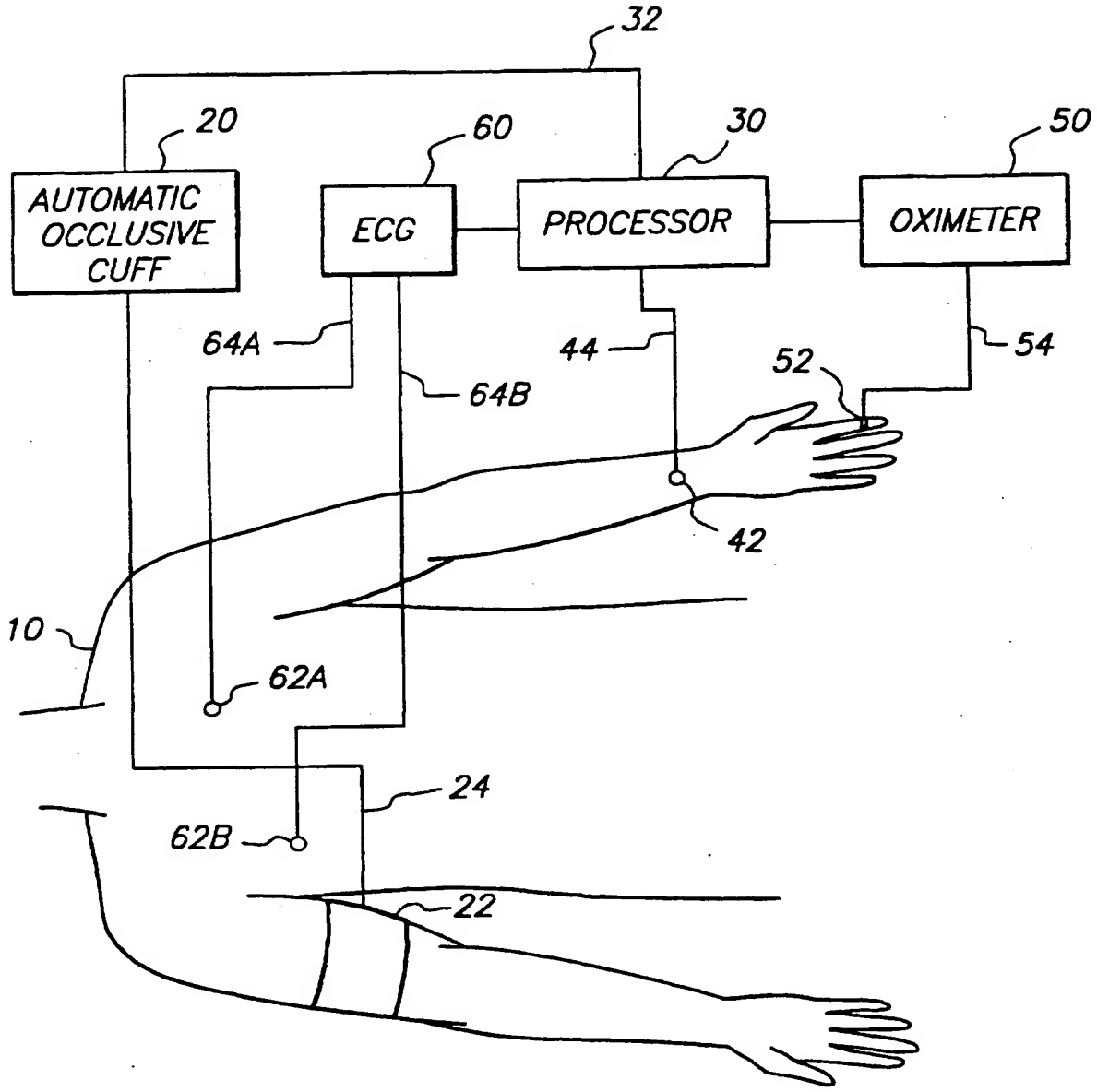
62A
24
62B
22

FIG. 7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AUTOMATIC OCCLUSIVE CUFF
ECG
PROCESSOR
OXIMETER
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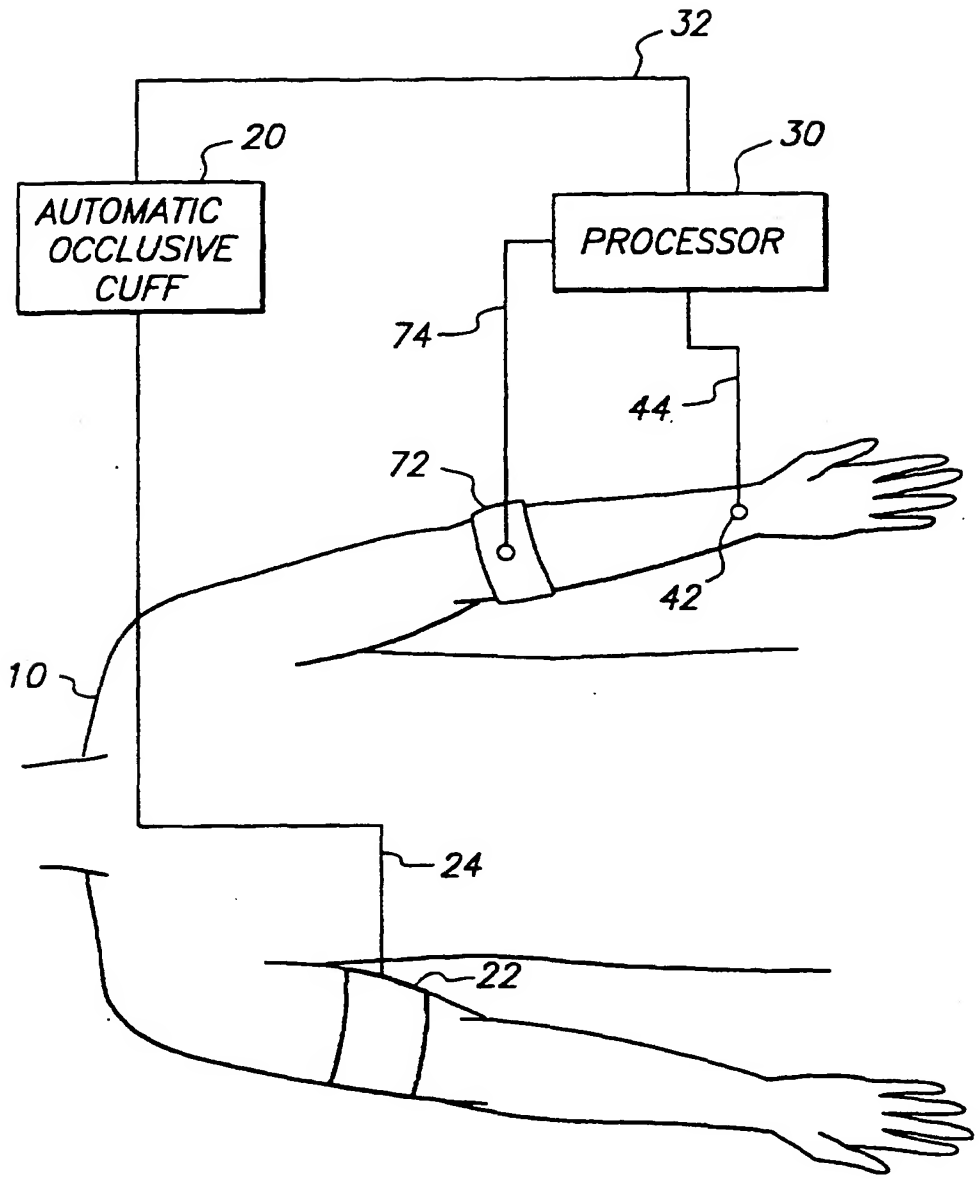
24
62B
22

FIG. 8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AUTOMATIC OCCLUSIVE CUFF
PROCESSOR
74
44
72
42
10
24
22

FIG. 9

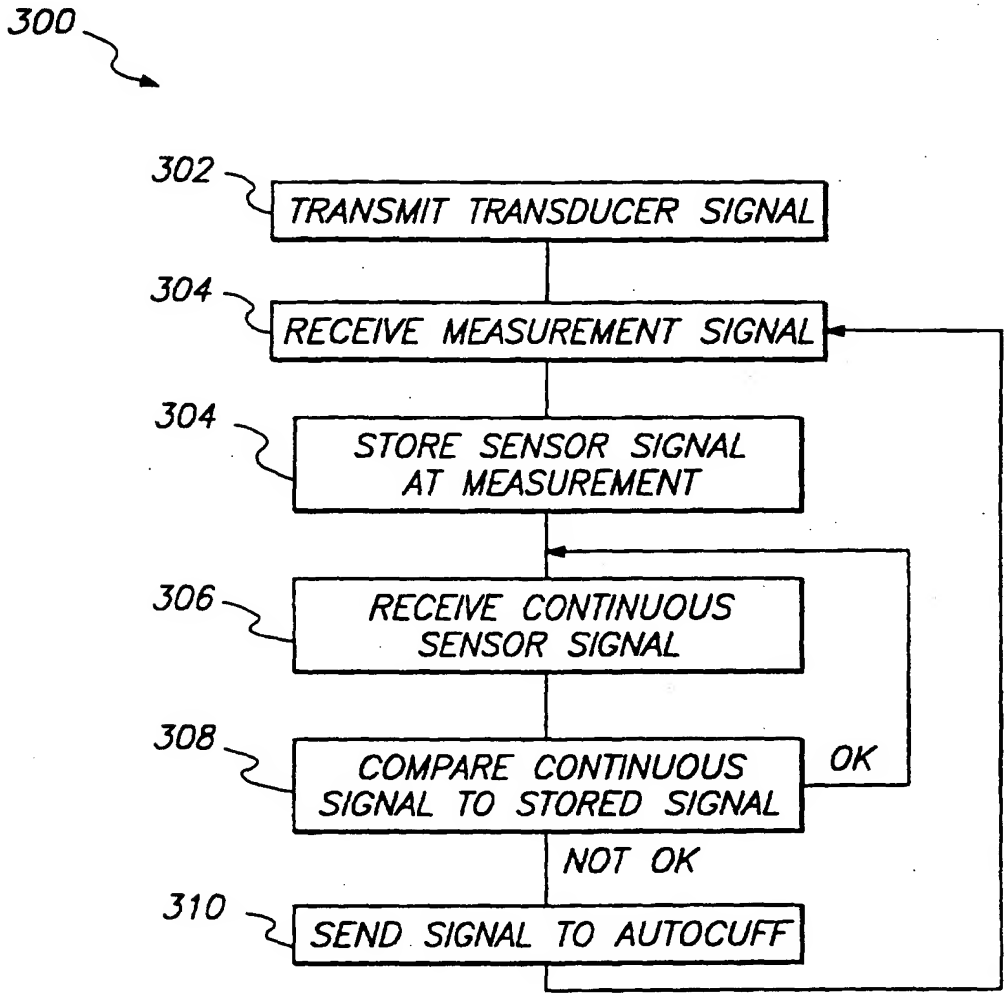
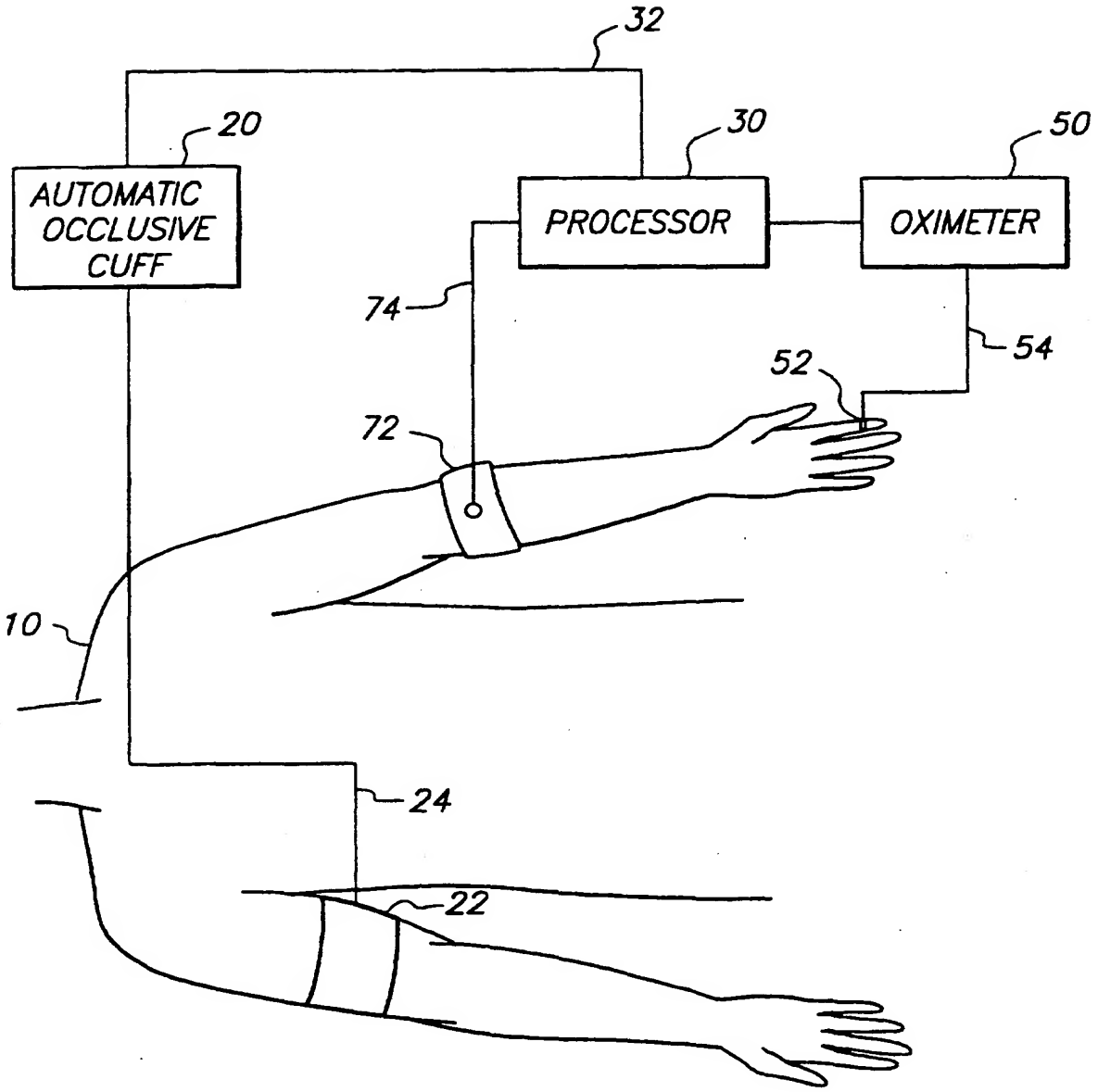

300
302
TRANSMIT TRANSDUCER SIGNAL
304
RECEIVE MEASUREMENT SIGNAL
304
STORE SENSOR SIGNAL AT MEASUREMENT
306
RECEIVE CONTINUOUS SENSOR SIGNAL
308
COMPARE CONTINUOUS SIGNAL TO STORED SIGNAL
OK
NOT OK
310
SEND SIGNAL TO AUTOCUFF

FIG. 10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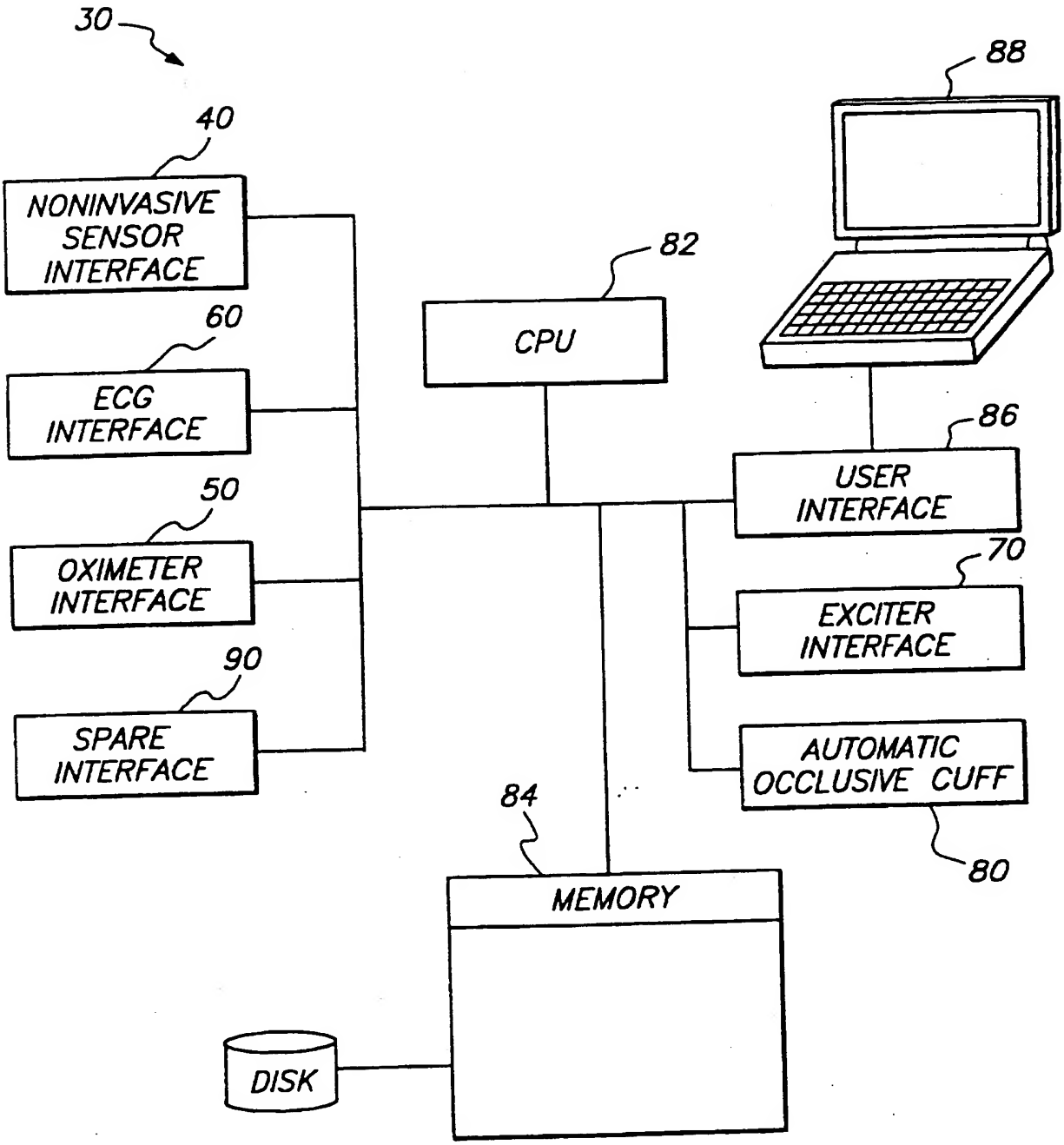
AUTOMATIC OCCLUSIVE CUFF
PROCESSOR
OXIMETER
74
54
52
72
10
24
22

FIG. 11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88
40
NONINVASIVE SENSOR INTERFACE
82
CPU
60
ECG INTERFACE
86
USER INTERFACE
50
OXIMETER INTERFACE
70
EXCITER INTERFACE
90
SPARE INTERFACE
AUTOMATIC OCCLUSIVE CUFF
84
80
MEMORY
DISK

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/12452

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 05/00
US CL :128/668;
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/667, 668, 670, 672, 677-683, 687-694, 748

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US, A, 5,111,817 (CLARK ET AL.) 12 May 1992, see entire document.	1-4, 12--20 --- 5-11, 21-32
A	US, A, 5,237,997 (GRUEBEL ET AL.) 24 August 1993, see entire document.	1-32.
A	US, A, 5,241,964 (McQUILKEN) 07 September 1993, see entire document.	1-32
A	US, A, 5,309,916 (Hatschek) 10 May 1994, see entire document.	1-32

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date f the actual completion of the international search	Date f mailing of the international search report
20 NOVEMBER 1995	29 DEC 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROBERT NASSER Telephone No. (703) 308-3251

Form PCT/ISA/210 (second sheet)(July 1992)*

SDOCID: <WO_ . 9611625A1_IA>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/12452

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- A	US, A, 5,279,303 (KAWAMURA ET AL.) 18 January 1994, see entire document.	1-3, 5, 12-19, 21 --- 4, 6-11, 20, 22-32.

Form PCT/ISA/210 (continuation of second sheet)(July 1992)*

ISDOCID: <WO 9611625A1 IA>